

CREATING VALUE: CRITERIA AND CONSIDERATIONS FOR THE DEVELOPMENT OF A SUSTAINABLE NATIONAL SYSTEM

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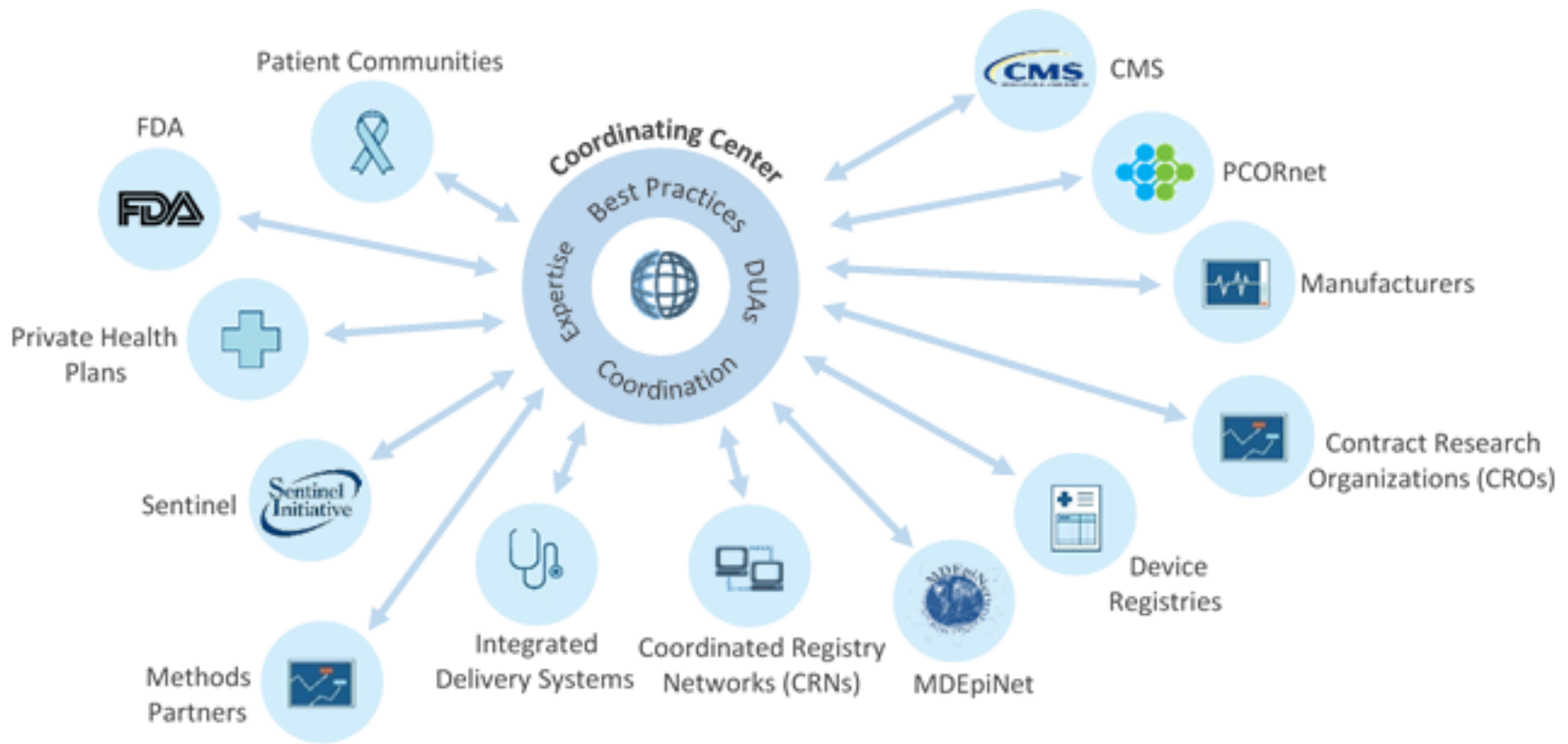
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HISTORY OF THE PLANNING BOARD

- Phase I (Fall 2014)
 - Articulate a long-term vision for a National System
 - Recommend strategies for implementation
 - February 2015 report “*Strengthening Patient Care: Building an Effective National Medical Device Surveillance System*”
- Phase II (Fall 2015)
 - IIa: Define the objectives and capabilities of the Coordinating Center
 - April 2016 Report “*Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System*”
 - IIb: Identify potential demonstration projects and strategic priorities for development of the Coordinating Center
 - Paper planned to be released in August 2016

NESMD



STRATEGIC DEVELOPMENT

- Identify and facilitate “cooperative advantages” and partnerships
 - Stakeholder surveys
 - Patients
 - Providers
 - Manufacturers
 - Payers
 - Pilot questionnaire
 - Expert interviews
- Build the National System shared resources and infrastructure through demonstration projects AND showcase the value of the Coordinating Center approach

EVALUATION CRITERIA

Demonstration projects can guide the strategic development of the future Coordinating Center

- **Impact** – What is the size and scope of the project's benefit for stakeholders?
- **Feasibility** – Can the project attract sustainable funding and align with the Center's development timeline?
- **Center sustainability** – Does the project build reusable infrastructure and frameworks that incentivizes continued engagement from system partners?

DEMONSTRATION PROJECT PROPOSALS

- Demonstration projects designed to target use cases for key stakeholders
 - Adverse event reporting
 - UDI integration
 - Patient-centered data commons
 - Medical device reimbursement
 - Registry with embedded-IDE trial
 - And more...
- Need to strike the right balance between the interests of the stakeholder(s) and building the national system

THANK YOU

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