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The National Medical Device Evaluation System (NMDES): Planning Board Update

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Value of Coordination of Medical Device Real-World Evidence Activities

- Supports FDA's dual mission
  - Protect patients from unsafe medical devices
  - Ensure the timely availability of new and improved medical technologies.
- Close significant gaps and delays in safety surveillance
- Develop better device clinical effectiveness data based on real-world evidence
- Develop value evidence for clinicians and payers
- Reduce development time, cost, and uncertainty for safe and effective medical devices

Planning Board

- Established in Fall 2014 to guide the development of the NMDES under a cooperative agreement with CDRH
  - February 2015 report “Strengthening Patient Care: Building an Effective National Medical Device Surveillance System”
- Reconvened in Fall 2015
- Phase II objectives
  - Define the objectives and capabilities of the Coordinating Center
  - Identify demonstration projects that will engage stakeholders to develop the infrastructure of the National System
  - Recommend strategic priorities for development of the Coordinating Center

Vision for NMDES

- NMDES is envisioned as a strategically-driven, coordinated network of voluntary partnerships working towards generating higher quality data at lower costs to inform and improve patient care.
  - Institutional data partners
  - Methods partners
  - Patient communities
- Multi-stakeholder public-private partnership
  - Incrementally scales up infrastructure
  - Evolves with lessons learned and evolving stakeholders' needs
  - Clear, transparent system governance
  - Continuous system performance evaluated by a Coordinating Center

Key Principles for the NMDES

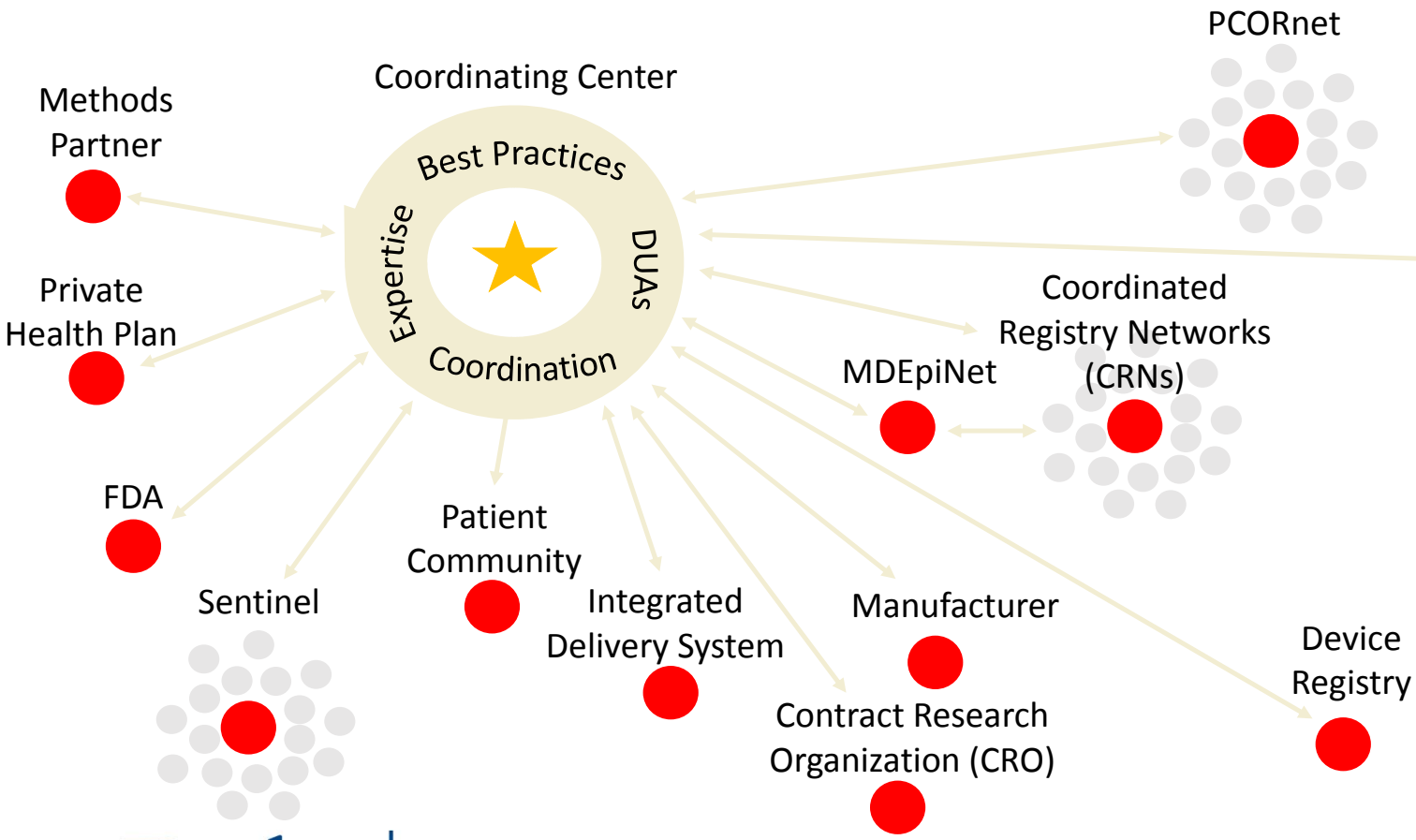
- **Gateway**: Ensure broad voluntary access to resources
- **Patient-focused**: address questions of high interest to patients and the clinicians that care for them
- **Innovative**: Improve real-world data to enable companies to compete on quality of products instead of the costs of generating data
- **Re-usable and scalable**: draw on and collaborate with existing activities to facilitate re-usable connections between data partners for multiple uses
- **Trustworthy**: create trust by engaging patients and other stakeholders through representative governance and transparent communication
- **Clear expectations and policies**: Protect manufacturer's intellectual property while allowing responsible access by other analysts and clear criteria for reporting/sharing results

Coordinating Center

Mutually Beneficial Shared Resources

- Establish a re-usable network of data partners through standardized data use agreements
  - Expedite project-specific research agreements with sponsors and/or qualified methods partners.
- Access to expertise and advanced methods, tools, standards and best practices
  - Detect safety events
  - Study clinical effectiveness of new technologies for regulatory and reimbursement decisions
- Source of reliable, up-to-date and trusted information on medical devices' risks and benefits for patients and the broader health community
  - Safety updates, recall management support, emerging effectiveness information

NMDES - Network of Partners



- Non-centralized system
- Reusable pathways
- Built fit-for-purpose

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Potential Role of Coordinating Center in Partnership with CRNs

Work with CRNs, MDEpiNet, and other stakeholders to:

- **Develop reusable frameworks to connect CRNs to other sources for more timely and cost efficient data linkages**
  - CMS
  - PCORnet
- **Disseminate key findings and best practices**
  - Draw attention to critical research for the general public and key decision-makers
  - Expand best practices to *ad hoc* "virtual registries" for lower risk devices
- **Support adoption of validated methodologies and tools**
  - UDI adoption in claims and EHRs
  - DELTA – data extraction for near real-time active safety surveillance of (EHR) or clinical registry data
  - SMART/VANGUARD – Minimum data sets for registry development
- **Support nontraditional registry activities**

Potential Demonstration Projects

Safety

- Quantify potentially serious but rare adverse events in Class II devices
  - Link EHR and claims data to generate a retrospective "virtual registry" using information collected through routine patient care to calculate real-world event rates.
- Automated efficient safety surveillance
  - Expand the use of tools like DELTA for active surveillance with registries
  - Use registry information to reduce reporting burden for common known adverse events

Re-purpose infrastructure for effectiveness evaluations

- Enhance existing registries while balancing data entry burden
  - Partner with PCORnet and provider systems to standardize and automate data entry for information collected through routine patient care from EHRs
- Partner with payers to generate effectiveness information for coverage decisions

Patient-driven evaluation systems

- Promote methods for direct data collection from patients, including patient-reported functional status, safety problems, and other outcome information

Planning Board: Next Steps

- White Paper release on April 1
- Engage with stakeholders (e.g., patients, clinicians, payers, industry) to understand their priorities for the system
- Survey the landscape of existing activities to identify high-priority activities and gaps in current abilities
- Identify demonstration projects to develop the infrastructure of the National System

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Thank you