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Better Evidence on Medical Devices:

A Coordinating Center for a 21st Century National Medical Device Evaluation System

National medical device evaluation system
Planning Board Report

April 2016

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About the Duke-Margolis Center for Health Policy

The Duke-Robert J. Margolis, MD, Center for Health Policy, founded with a gift from Duke University School of Medicine alumnus Robert J. Margolis and his wife Lisa, connects the intellectual resources at Duke with policymakers and policy analysts in the public and private sector. Disciplines involved in the Duke-Robert J. Margolis, MD, Center for Health Policy will include business, biomedical research, clinical care, public policy, global health, law and other areas.

The Duke-Margolis Center has staff and offices in both Durham and at Duke's center in Washington, D.C. It has participation from faculty and staff at Fuqua, Sanford School of Public Policy, School of Medicine, School of Law and other units, and collaborates with experts and health care reformers from across the country and around the world. The center's activities include serving as a hub for translational policy research and analysis - that is, for supporting the movement of promising ideas in health reform into the implementation of effective policy.

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Preface

In 2014, the U.S. Food and Drug Administration (FDA) and Brookings Center for Health Policy convened a national medical device evaluation system Planning Board (Planning Board). The Planning Board is a multi-stakeholder group with representation from patients, clinicians, researchers, provider organizations, health plans, industry, and experts in health information systems, as well as key government agencies, including FDA, NIH, AHRQ, CMS, and ONC. It was tasked with the goal of creating a long-term vision for a sustainable national system to evaluate the risks and benefits of medical devices. The Planning Board released its first report, *Strengthening Patient Care: Building an Effective National Medical Device Surveillance System*, in February 2015. This report included recommendations for the system mission, functions, governance principles, operational components, and a strategic plan to develop and implement the system. In late 2015, FDA asked the Duke-Margolis Center for Health Policy to reconvene the Planning Board to help lead the next phase of the system's coordinating center and governing body development.

This is the first of a series of papers to be released by the reconvened Planning Board to promote and support public discussion of how to address the pressing need and opportunities for better evidence on medical devices. It outlines preliminary recommendations from the Planning Board on the objectives, tasks and capabilities of a new Coordinating Center that will be charged with the development of a national medical device evaluation system (NMDES).

While this project is supported through a cooperative agreement with FDA, the views expressed in this paper are those of the Planning Board members, and do not necessarily reflect the official policies of the Department of Health and Human Services, nor does mention of specific projects or organizations imply endorsements by the U.S. Government or other organizations.

Introduction

Despite the critical role of medical devices in the diagnostic and therapeutic care of patients and the growing availability of real-world electronic health information collected routinely across the spectrum of care, the medical device ecosystem lacks coordinated and efficient systems for developing actionable evidence on safety and effectiveness.

A range of public and private efforts are underway that seek to address these gaps, reflecting substantial investments from FDA, clinical researchers, private industry, and others. Examples include networks and collaborations such as the Medical Device Epidemiology Network Initiative (MDEpiNet), the Medical Device Innovation Consortium (MDIC), multiple Coordinated Registry Networks (CRNs), and the Patient-Centered Outcomes Research Network (PCORnet). Specialized registries such as the Transcatheter Valve Therapy (TVT) Registry and the American Joint Replacement Registry (AJRR) are providing evidence on some important implantable devices. While these initiatives have helped provide proof of concept that better evidence on medical devices is feasible, they have also identified ongoing limitations. These limitations include the absence of broad adoption of unique device identifiers (UDIs) to track medical devices, despite promising pilots such as that undertaken by Mercy Health System; high costs of manual data entry and delays in data extraction for use, because electronic records cannot be readily and reliably used to support device tracking; and limited participation by health care providers and patients in many tracking efforts.

As a result, reliably and efficiently tracking the medical device safety and effectiveness outcomes of most interest to patients remains a generally unfulfilled promise of current systems. The absence of these capabilities significantly affects the public health and biomedical innovation, by creating obstacles for patients and clinicians to receive the meaningful information they need to make informed decisions, perpetuating unnecessarily long delays and gaps in effective and timely safety communications and recall management, hindering the timely development of new and innovative treatment options, and increasing the overall costs and inefficiency of the health care system. To improve the ability of patients to receive high quality, safe, effective, and timely care, better information about medical devices must be a priority as the nation builds the capacity to harness electronic health information to improve health, care quality, and safety.

NMDES Mission

Support optimal patient care by leveraging the experiences of patients to inform decisions about medical device safety, effectiveness, and quality in order to promote the public health.

To this end, CDRH's 2016-2017 Strategic Priorities include the establishment of a national medical device evaluation system with the goal of increasing access to and use of real-world evidence to support regulatory decision making and technological innovation.[i] This goal aligns with the recommendations made in the 2015 reports released by both the Planning Board[ii] and MDEpiNet's Registry Taskforce[iii]. The Planning Board believes that there is an unprecedented opportunity for a more coordinated national approach that addresses the broader needs of patients, clinicians, health care insurers, and medical device manufacturers, as well as FDA.

What is a National Medical Device Evaluation System?

NMDES is envisioned as a strategically-driven, coordinated network of voluntary partnerships that include patient communities, government agencies, device manufacturers, institutional data partners, and methods partners, all working towards generating higher quality data and evidence at lower costs to inform and improve patient care.[iv,v] NMDES should support the development of mutually beneficial resources that expedite the generation of reliable information about medical devices to promote public health. These resources should include:

- Data from multiple sources (including electronic health records, claims, registries, patient reported outcomes, clinical trial data, etc.) connected through re-usable, standardized data use agreements (DUAs) that optimize data standardization, expedite project-specific research agreements, and reduce the cost of evidence development through economies of scale
- A clearinghouse of expertise and advanced methods, tools, standards, and best practices (e.g., to detect safety events and to study clinical effectiveness of new technologies for regulatory and reimbursement decisions)
- A trusted and up-to-date compilation of reliable information on the benefits and risks of medical devices for patients and the broader health community (e.g., safety updates, recall management support, emerging effectiveness information)

NMDES should seek to enhance patient protections from unsafe medical devices while simultaneously ensuring the timely availability of new and improved medical technologies.

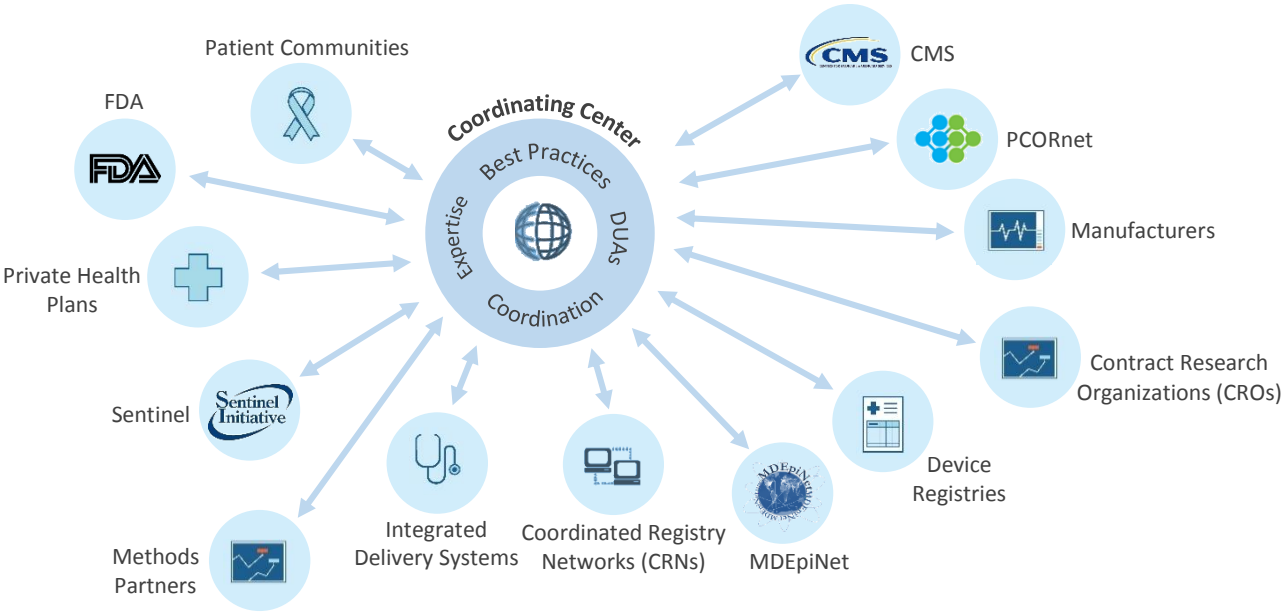
The current evidence development ecosystem is composed of a range of databases, projects, and registries that are typically device- or therapy-specific and provider-focused instead of patient-focused. While many produce high-quality, useful, and reliable information, they generally focus on a small number of high-risk medical devices and are narrowly targeted with shorter-term outcomes. The individual activities do not have support to take advantage of opportunities to expand their utility at lower cost for addressing the most important evidence questions. In many cases, their potential to reduce regulatory burdens – for example, through routine active safety surveillance reporting – remains untapped or underused. NMDES should work towards expanding and enhancing these current efforts, increasing their efficiency and capabilities, and creating opportunities to generate better evidence in new areas through governance, coordination, and standardization (Figure 1). Examples of high priority opportunities include:

- Expanding the capabilities and improving the efficiency of traditional registries by utilizing the best practices of high-performing registries and international consortiums to incorporate evidence generation to inform pre- and postmarket regulatory decisions (e.g. linking information on longitudinal outcomes, advanced analysis techniques). In addition, opportunities exist to
    - Create alternate pathways that use registry information to provide more valuable rate-based information on labeled outcomes than currently possible through individual Medical Device Reports (MDRs)
    - Automate data entry and standardize outcome measures to allow evidence generation for effectiveness (including comparative effectiveness) while minimizing data collection burden

- Improving the reach of innovative analytic tools such as machine learning and the DELTA System for broader and more comprehensive active safety surveillance across a range of devices and data systems

As envisioned, NMDES is a flexible, virtual system that builds on and supports existing activities that are generating evidence on medical devices as well as evidence relevant to many other purposes, such as enhancing quality of care and care coordination. It would undertake specific activities to improve safety surveillance and enable more efficient FDA decision-making, and support the use of the same interoperability-focused connections and tools by other stakeholders for their evidence development needs, such as premarket approval and clearance as well as payer coverage and reimbursement. NMDES would be constantly identifying new sources of reliable device data and designing and implementing innovative ways of capturing and combining data from disparate sources while ensuring that federal patient-privacy laws, regulations and ethical standards are maintained.

Figure 1. NMDES as a Coordinated Network of Partners



The Coordinating Center will act as a non-hierarchical body that provides governance, coordination, and standardization to organizations within the medical device ecosystem. The Coordinating Center will build mutually beneficial shared resources and reusable pathways with standardized data use agreements (DUAs) to drive down the time and cost of generating evidence on medical devices.

Table 1 lists some of the benefits of NMDES to various stakeholders as well as their potential contributions. As the table highlights, building NMDES with a patient-centric focus has important benefits for all stakeholders. It would allow patients and clinicians access to better information on the benefits and risks of devices based on the real-world evidence. Health insurers would have access to vital information to determine what products best meet the needs of their beneficiaries. Manufacturers would be less limited

Table 1. Contributions and Benefits of NMDES to Patients and Other Stakeholders

Stakeholder	Voluntary Contributions	Benefits

Patients	• Patient engagement
	• Patient-generated health information
	  ○ Outcomes
	  ○ Quality
	  ○ Adverse events
	• Funding from patient groups
		• Safer and more effective medical devices
		• Faster access to trusted, personalized medical device safety and effectiveness information
		• Faster access to innovative medical devices as a result of streamlined evidence development and regulatory processes
		• Trusted, accessible source of information about devices in the news.

Clinicians and Hospitals Systems	• Routinely-generated clinical data • Discharge and care management information • Communication channels to share safety information • Content expertise • Methodology • Funding for research studies	• Safer and more effective medical devices • Faster access to medical device safety information • Faster access to innovative medical devices as a result of streamlined evidence development and regulatory processes and reimbursement processes • More timely and higher quality information on the performance of medical devices in real-world settings • Optimized device selection for specific patient cohorts • More information on medical device and operator performance • Streamlined adverse event reporting
FDA and other regulatory agencies	• Regulatory authority • Adverse event data • Content expertise • Methodology • Funding for NMDES development	• Embedded NMDES data collection allows more efficient compliance • Active safety surveillance for faster signal generation, refinement, and validation • Better understanding of device performance over time and in clinically diverse populations • Product tracking for recall management • Incubator for future patient safety coordinating functions

Manufacturers	• Proprietary device and registry data
	• Content expertise
	• Funding for research studies and NMDES development
		• Streamlined adverse event reporting
		• Lower cost and more efficient system for generating safety and effectiveness evidence
		  ○ Support pre- and postmarket regulatory submissions
		  ○ Support coverage and reimbursement decisions
		• Faster, less costly access to market for innovative technologies through reduced burden for pre-market data collection
		• Streamlined access to patient communities (including hard-to-capture subpopulations) for recruitment and engagement

Health insurance organizations	• Claims, administrative, and utilization data • Content expertise • Health economic analysis • Funding for research studies and NMDES development	• More timely and relevant information on medical device performance, quality, and value • Improved ability to support higher quality and lower cost care through more timely and actionable evidence • Ability to participate in and perform more relevant comparative effectiveness research and health economic research on medical devices
Research organizations	• Content expertise • Methodology • Funding for research studies and NMDES development	• More sources of standardized and high-quality data on medical devices • Longitudinal safety information on medical devices • More information on medical device and operator performance • Optimized patient selection criteria • Reduced cost and burden to conduct comparative effectiveness research and health economic research on medical devices

by the cost of generating data and would have the ability to improve their products and compete on the basis of quality.

Objectives and Tasks of the Coordinating Center

The proposed Coordinating Center would provide governance, coordination, and standardization to drive down the time and cost of generating evidence on medical devices, while increasing the accessibility and usability of real-world data. The Coordinating Center should ultimately be responsible for creating opportunities for better and more efficient evidence generation and evidence sharing through coordinating and facilitating effective use of the Coordinating Center's methods partners' expertise and the network of data partners by diverse public and private stakeholders. This includes managing the incremental development of, as well as facilitating access to, NMDES's shared resources (described above). The Coordinating Center should work closely with stakeholders across the device ecosystem to assess their needs, and facilitate demonstration projects that leverage current activities to more effectively meet those needs while also strategically building a system focused on the reusability and interoperability of data, network linkages, and tools. The Coordinating Center should continually engage stakeholders to understand their emerging needs and monitor innovation to ensure that NMDES is flexible and adaptable.

In order to ensure that all stakeholders can effectively participate and engage in the governance and development of NMDES resources, the Planning Board recommends that the Coordinating Center be instituted as a public-private partnership, organized as a nonprofit entity with both public and private representation on its Governing Board. Some of the activities facilitated through the Coordinating Center should be in partnership with, and in support of, FDA's and other agencies' regulatory authorities as well as to support the needs of the private sector. While the Coordinating Center would not have explicit regulatory authority, it would be possible for FDA's authorities to work through the Coordinating Center in a similar way drug surveillance activities are conducted under the Sentinel System.[1] Another potential model is the Medical Device Innovation Consortium (MDIC), which works in partnership with FDA to improve regulatory science.[2] Ideally, non-governmental organizations will voluntarily seek to partner with the Coordinating Center based upon simplified access to high-quality services and resources that facilitate the expedited execution of high quality research and public health evidence development activities more effectively and at a lower cost than the current model. For example, the Coordinating Center could assist mid-size and small manufacturers by identifying appropriate analytic tools and/or facilitating use of the network of partners so that they are able to more efficiently conduct

[1] FDA authorizes substantial funding towards the Sentinel System to engage in active surveillance queries for pharmaceutical products on their behalf. FDA-authorized and initiated queries fall under the public health exemption of the Common Rule. Certain activities facilitated by the Coordinating Center and run by experimental partners on behalf of FDA could fall under the same exemption.

[2] MDIC is a nonprofit 501(c)3 public-private partnership that collaborates with FDA, CMS & NIH, industry and other nonprofits to improve the medical technology environment through the development of methods, tools and processes in the pre-competitive space.

Table 2. Objectives of the NMDES Coordinating Center

Coordinating Center Objectives	Description
Functional Objectives	
Optimize the cost of, access to, quality of, and sharing of data related to the evaluation of medical devices	The Coordinating Center should create a coordinated network of data partners by promoting UDI adoption, standardized data sharing agreements, interoperability, and automated data collection and extraction while committing to rigorous privacy, ethical, and data security protections.
Promote the adoption of best practices for device evaluation	The Coordinating Center should develop a clearinghouse of best practices for evaluating the safety and efficacy of medical devices that is easily accessible to researchers and the public.
Develop a transparent and streamlined process for evaluating and disseminating medical device safety and effectiveness information	The Coordinating Center should promote methods for evaluating emerging safety signals and the dissemination of accurate and informative safety information to patients, clinicians, and policymakers in a responsible, timely, and accurate manner.
Organizational Objectives	
Establish governance components for NMDES and the Coordinating Center	A governing board, expert committees, and an executive director will need to be identified and selected by the Coordinating Center early on. The governing components will be critical towards setting the policy agenda for NMDES activities.
Develop a sustainable business model for a national medical device evaluation system	The Coordinating Center should be the central body responsible for promoting the long-term sustainability of NMDES through both public and private funding sources.

FDA-mandated pre- and postmarket studies as well as any additional studies needed to support reimbursement and coverage decisions.

All NMDES activities should be based on partnerships. Therefore, it is critical that NMDES be founded on a clear set of principles and priorities shared by those partners. Most importantly, NMDES must gain the trust of the public and other stakeholders through clear expectations and transparent communication that reflect a focus on relevant evidence for patients. NMDES should be part of the wider learning health care system and continually evolve as technology changes. Appendix A includes a more detailed set of principles and essential uses of NMDES.

In order to accomplish the vision of the NMDES, the Planning Board proposes the set of Coordinating Center objectives listed in Table 2. Functional objectives are focused on building the shared resources of NMDES. Organizational objectives focus on governance and sustainability of the Coordinating Center.

Functional Objective: Optimize the sharing of medical device data

A primary objective of the Coordinating Center is to optimize the cost of, access to, quality of, and the sharing of medical device real-world data for evidence development, while affording strong ethical and

privacy protections. The Coordinating Center should be responsible for creating a data governance structure as well as soliciting and managing re-usable, standardized data use agreements with partners such as the Patient-Center Outcomes Research Institute (PCORI), Sentinel, provider and payer systems, and manufacturers. The data use agreements are intended to create a gateway that expedites access to data on medical devices while ensuring the responsible use of that data through governance policies and providing equal access to the network of data partners. The data governance should be grounded in NMDES principles (see Appendix A), focused on data interoperability, and committed to rigorous privacy, ethical, and data security protections.

Beyond the development of the network of data partners, the Coordinating Center should also work to identify and advance solutions to programmatic and/or policy challenges that influence the ability to share and responsibly use data. The Center should undertake specific collaborative initiatives to make practical progress on long-standing challenges to effective postmarket evidence generation. These initiatives might include adopting UDIs,[vi] standardizing and streamlining informed consent, ensuring privacy, enabling appropriate patient identification and matching, and providing the security needed to accelerate data sharing. It would do so in the context of specific opportunities to create better, lower-cost postmarket evidence on high-priority topics. For example, there is currently work being done to link additional data sources to registries on high-risk devices in order to obtain longitudinal outcome data.[vii] The Center could undertake a focused initiative with federal and private partners to facilitate the process and lower the cost of generating data related to early failures and the long-term risks of particular high-risk devices, and addressing other effectiveness or outcome issues of high interest to patients, FDA and payers. Other initiatives could investigate innovative ways to reduce the burden of data collection on clinicians and other providers, through automated data entry, common data models and definitions, and patient-focused standardized therapeutic measures. Each initiative will incrementally expand on the capabilities and lessons learned previously. For example, connections made and techniques developed during initiatives promoting UDI adoption in health IT systems, cost-effective linkage functionality, automated data entry, and standardized outcome measures could potentially be combined into a project to create virtual *ad hoc* registry-type information for a lower-risk and/or high-volume device for which a formal registry might be cost prohibitive. This information could be generated through an automated query of claims and health IT data through the network of data partners. This type of virtual just-in-time-type registry could be expanded and used for efficient and cost-effective safety surveillance, evidence development for indication expansions or coverage decisions, comparative effectiveness research, or to answer other research question utilizing real-world evidence. Other models will be explored as well.

In an ideal medical device ecosystem, data generated from clinical trials and premarket activities would be seamlessly joined to data generated in the postmarket period. All data on a particular device would be incorporated into a comprehensive body of evidence regarding its efficacy, safety, and effectiveness, which could be used to inform the next iteration of the device or an innovative new product. Seamless data flow is currently interrupted by the lack of adoption of universal standards for data exchange, uncertain business cases for data exchange, concerns regarding the Health Insurance Portability and Accountability Act (HIPAA), institutional risk-aversion, and concerns about costs. The Coordinating Center should be charged with promoting more effective data use throughout the medical device life-cycle and among data partners.

Functional Objective: Promote adoption of best practices for device surveillance and evaluation

The Coordinating Center should be a trusted curator of best practices regarding data collection, exchange, and evaluation. The Coordinating Center should routinely evaluate NMDES activities for best practices and survey the medical device ecosystem for innovative methods and disruptive technologies. The Coordinating Center should aggregate this knowledge into an easily accessible clearinghouse that promotes dissemination of lessons learned and implementation of best practices.

Functional Objective: Develop a streamlined and transparent process for evaluation and dissemination of safety and effectiveness information

The Coordinating Center should enable more effective and timely information on medical devices by supporting the establishment of transparent criteria and processes for evaluating and disseminating safety and effectiveness information. The Coordinating Center should advance the development of expert-developed guidelines for evaluation and patient-focused processes for responsible dissemination.

Information regarding the safety and effectiveness of medical devices must be carefully evaluated prior to dissemination. False adverse event signals or spurious claims of efficacy pose real dangers to patient populations. FDA serves as the principal arbiter of when information regarding medical device safety and efficacy should be made public. However, a gap in reporting may exist when the signals generated are unclear or below the threshold for regulatory action. Scientific journals and peer review can be effective in evaluating the quality and accuracy of claims but suffer from slow diffusion and limited audiences. The Coordinating Center should serve as a trusted source by actively disseminating and storing relevant evidence concerning medical devices. This process should also allow for competing analytic approaches and presentation of various viewpoints about the applicability of findings, so that the data produced by the medical evidence system is better understood and more useful.

Organizational Objective: Governance of the Coordinating Center

The Coordinating Center should devote early resources to implementing a streamlined and nimble governance approach for oversight. Among the first tasks of the nascent organization will be to hire an executive director for the Coordinating Center and to establish the Governing Board. The executive director should be responsible for the day-to-day operations and, once it is established, liaise with the Governing Board on behalf of the Coordinating Center. The Governing Board should be nominated and selected through a public and transparent process, with the intent of ensuring that key stakeholders are represented (see Appendix B).

Organizational Objective: Sustainability of a National System

Real-world evidence is being used today in regulatory and non-regulatory decision making, and there are notable examples of both the value and challenges in using such data. The Coordinating Center should be accountable for demonstrating the return on investment in NMDES in its early stages. The Planning Board believes this will be best achieved through a series of very near-term, high-value, multi-organizational demonstration projects involving the Coordinating Center. These projects should prove the capability, value and increased efficiencies of the functions that underlie the National System while continuing to build the system's capacity to meet its essential public health uses, as described in Appendix A. Early high priority demonstration projects could include augmenting and improving the utility of an existing registry by efficiently linking the registry with other data sources and data types and thereby allow for broader

uses and increased longitudinal follow-up; creating an innovative virtual registry using health IT and claims data from a Class 2 device with potentially serious but rare adverse events; and working with FDA to identify less burdensome methods for industry and registries to work together to report adverse events.

The Coordinating Center will need to develop enough value from these efforts that a sustainable business model that promotes strategic engagement and partnerships while remaining focused on patients can be achieved. Early seed funding from the public sector would establish the Coordinating Center and enable focused early demonstration projects that illustrate this value, which should be augmented with financial support from vested stakeholders including industry partners, other agencies, and research organizations. Once operational, multiple potential revenue streams could be developed to support the Coordinating Center, including transactional fees-for-services and membership dues for continued shared infrastructure building and maintenance. However, given that many of the benefits of NMDES accrue to the public and not to specific companies or stakeholders, a sustainable system will continue to require a combination of both public and private funds.

At the same time, NMDES's clear value to diverse stakeholders will be key to its sustainability. The Coordinating Center will need to develop performance and outcome metrics that evaluate on an ongoing basis the Center's progress meeting the mission of NMDES and on providing value to its partners. The performance and outcome metrics for the Coordinating Center could include process measures related to the development of the shared resources, but also measures that focus on the real desired outcomes of generating and disseminating higher quality data to inform and improve patient care at lower costs.

To show commitment to the system principle of gaining trust through clear expectations and transparent communications the Governing Board, in conjunction with the Coordinating Center, should commit to publishing annual reports on this ongoing performance evaluation, as well as announcing pre-determined metrics that will be used in the reports. These metrics should assess the system's performance in generating and disseminating information that patients care about, the continued engagement of stakeholders in the system, and the use and usability of the clearinghouse of best practices and tools information. It should also provide quantitative measures of the costs and benefits of studies using the system compared to independent studies.

Conclusion

At present, there is a critical public health need to establish a Coordinating Center that will have the ability to act as a long-term and broad-based strategic coordinator of efforts to bring together, organize, evaluate, and secure medical device data. We are entering a world with previously unimaginable amounts of medical device data and the potential for much more sophisticated understanding of health and medical issues. To reach the goal of providing better information and care for patients, a coordinated effort to establish broadly-supported processes and policies for medical device data sharing, protection, and evaluation is needed. Major efforts to enact institutional and cultural change across the medical device community will require multi-stakeholder collaboration and cannot be sustained by federal or private action alone.

The Planning Board believes that achieving such a system would unlock numerous benefits to patients and the wider medical ecosystem. NMDES would allow patients and clinicians to benefit from personalized and more timely evidence about the safety and effectiveness of medical devices, leading to better health outcomes and avoiding unnecessary costs. It would complement the iterative nature of

medical device development and give manufacturers a faster, more predictable path to approval and reimbursement decisions. Once products are on the market, the NMDES would provide more cost-effective approaches to developing postmarket evidence, which will lead to greater confidence among clinicians in the products they use and recommend. Lastly, payers would be expected to benefit from having better evidence that improves their coverage decisions and from a system that can be leveraged to address other questions of interest to them.

Appendix A: Guiding Principles for the Coordinating Center

As the organizing center of NMDES, the Coordinating Center will need to be guided by the principles of NMDES[viii] to accomplish its mission of supporting optimal patient care to promote the public health.

Most importantly, the Coordinating Center needs to be patient- and clinician-focused. Patient and consumer advocates should be integrated into the Center's governance and the Coordinating Center should advocate for evidence generation that addresses questions of high interest to patients and the clinicians that care for them. In addition, it should create trust through clear expectations and transparent communication. Public trust in the policies, methods, tools, leadership and expertise of the people responsible for facilitating and overseeing the aggregation, evaluation and dissemination of findings will be critical to the success of the Coordinating Center.

The Coordinating Center will need to integrate NMDES into the wider learning health care system to ensure the systems are aligned, complementary, and reduce duplication, cost and time through the effective reuse of data. The Center needs be forward-looking and continually evolving in order to have the capacity and vision to advance with the health care ecosystem to maintain viability and value. In addition, the Coordinating Center will need to be cognizant of the balance between what data is needed and the burden that collection can cause. The Coordinating Center should promote mechanisms to seamlessly integrate data collection into care workflows, enable interoperability of data across systems, and support standards-based data collection and exchange, while actively working to ensure that compliance with applicable privacy, data security, and ethical standards are maintained by NMDES.

Essential public health uses

The Coordinating Center should be guided by FDA device evaluation priorities and should prioritize NMDES uses, termed "essential public health uses", which support FDA's regulatory ability to protect and promote the public health particularly for issues where existing tools are not adequate.

A shared understanding of the essential uses should guide decision-making regarding resource allocation, partnership development activities, and network building. The Planning Board recognizes that there are many other important uses of NMDES outside of these essential uses. Other system uses facilitated by the Coordinating Center must not interfere with or delay operations or results for the essential uses.

Figure A1 lists some proposed essential public health uses of NMDES. Activities conducted to meet FDA regulatory actions or policies, whether by the Agency or independent entities, fall under the essential uses of the Coordinating Center.

Safety surveillance

Short-term priorities should focus on enhancing the quality and accuracy of safety signals and the data generated to confirm or refute them, improving patient safety communications for device recalls and safety issues, defining the population of medical devices in use, encouraging adoption of UDI into electronic health systems, and improving interoperability and patient matching to allow easier communication between networked systems. Demonstration project selection should prioritize projects that would advance methods for signal generation, refinement and verification through passive and active safety surveillance.

Figure A1. Essential Uses of a National Medical Device Evaluation System

- Safety surveillance to support evidence-based decision-making, recall management, and safety communication.
  - Active safety surveillance
  - Passive safety surveillance
  - Recall management
  - Safety communication
- Activities to meet specific FDA evidentiary requirements
  - Studies to support premarket submissions
  - Post-Approval Studies
  - 522 Postmarket Surveillance Studies
  - Discretionary studies
  - Indication expansions
  - Label changes
  - Fostering appropriate shifts of premarket data collection to the postmarket setting

Evidence generation for regulatory requirements

Entities that fall under the Agency's regulatory authority are required to meet certain evidentiary requirements regarding the safety and efficacy of devices marketed and sold. Postmarket evidentiary requirements mandated through specific regulatory programs and studies supporting premarket submissions, indication expansions or label changes would be considered an essential use. The Coordinating Center should work towards more cost-efficient and timely access to high-quality data sources and catalogue best-in-class methodologies for targeted analysis of safety and efficacy.

Sustainability-supporting uses for a national medical device evaluation system

Beyond the essential uses, there are other activities that the Coordinating Center should support to develop evidence demonstrating the value, quality, and effectiveness of medical devices. These activities could include coverage decisions by CMS and private insurers, comparative effectiveness research, clinical performance benchmarking, quality improvement, and the development of clinical guidelines. By leveraging the reusable networks of data and methods partners, users facilitated by the Coordinating Center should be able to conduct these studies more efficiently and at lower cost. The Coordinating Center should also support innovation-focused activities that enable the safe and rapid development of cutting-edge technologies that bring clear value to patient populations. These sustainability-supporting uses should remain a priority as the Coordinating Center seeks to develop its business model, build partnerships and demonstrate its organizational value.

Appendix B: Recommended Capabilities for the Coordinating Center

The capabilities a Coordinating Center would need in order to perform the tasks described overlap considerably so they have instead been organized into organizational categories: administrative, business model development and management, contract and grants management, knowledge management, data network development, research management, and policy development and promotion. A timeline (Figure B1) with key deliverables concludes this section.

Given FDA's priority of establishing a functioning Coordinating Center in the near-term, it is unlikely that a *de novo* entity can be organized in that timeframe. It is more likely that the Coordinating Center will be incubated at an established hosting organization. Given competing governance and financial interests that would likely be inherent in any hosting arrangement, the Planning Board recommends that the hosting organization propose a plan to eventually spin off the Coordinating Center and the Governing Board into a financially stable, independent entity.

Administrative

The Coordinating Center will need to be legally structured in a way that allows federal representatives to sit on the Governing Board. Administrative and human resources capabilities (either internal or outsourced) will be necessary to quickly recruit and retain qualified staff in order to meet the implementation guidelines and timelines described later in this document.

Business model development and management

The Coordinating Center will need to develop and maintain functioning partnerships with both FDA as well as a diverse group of organizations and stakeholders. An organization's history of developing and maintaining partnerships with private stakeholders (e.g., patient groups, providers, manufacturers, and payers) and public sector entities will be an important consideration. Because these partners will have a variety of competing agendas, the Coordinating Center will need to define processes for mitigating conflicts of interest, managing competing stakeholder interests in developing the strategic plan and ensuring fair access to Coordinating Center resources (e.g., data network). A history of quickly initiating critical partnerships is preferred in order to support and facilitate early pilot projects that will demonstrate the functionality of NMDES.

The Coordinating Center will also need to demonstrate financial sustainability beyond FDA seed funding, possibly through matching funds secured by the hosting organization to support the core program development.

Contract & grants management

The Coordinating Center may be managing funding for demonstration projects, infrastructure building and other sponsored research. It will need the financial and legal oversight (either internal or outsourced) to effectively manage receiving and awarding large contracts and grants, as well as professional resources in place to effectively manage and oversee program finances. Proposals regarding how the Coordinating Center will manage conflicts of interest with the host institution would be useful. The Coordinating Center will also need to legally accept receipt of both private and public funding and have resources in place that can demonstrate success at securing competitive contracts and/or grants.

Knowledge management and best practices development

The Coordinating Center will be responsible for a continuous environmental analysis of medical device evidence development activities and practices and for the evaluation and dissemination of safety and effectiveness information as described in the Coordinating Center objectives. Access to research staff and resources to support these tasks is essential. There should be scientific and financial modeling expertise either within the organization or through the ability to bring in external expertise to support the evaluation of potential best practices, tools and standards for evidence development. These evaluations will be used to continuously update an accessible clearinghouse of information on medical device evaluation methods. To appropriately evaluate and disseminate information on medical device effectiveness and safety, the Coordinating Center will need access to expertise in synthetic review of both published and unpublished studies and knowledge of how to effectively circulate information to both health care providers and the broader public.

Data network development

While the Coordinating Center will not be hosting or storing data initially, it will be required to have an understanding of the differing regulatory, payer, and clinical use requirements in the medical device ecosystem to coordinate, manage, and advance a network of data partners focused on medical device evidence generation and analysis. The Coordinating Center will need to determine the type of data model that will best fit the needs of NMDES over time, understanding the advantages and disadvantages of each, and engage data partners to participate. Additionally, demonstrated experience (either internal or through an expert committee) across multiple medical devices through the total product life cycle and therapeutic areas would be preferred given the diversity of medical devices to be included in NMDES.

The Coordinating Center will need to propose ways to leverage investments already made by others in this domain, and be capable of developing strong partnerships with PCORnet, the NIH Collaboratory, Sentinel, MDEpiNet, etc., to promote synergies and avoid duplication. Technical, legal and regulatory resources with expertise in data linkages, health information technology interoperability, and standards development such as that used in cloud-based shared databases with rules and access governed by privacy and data protection agreements is critical to developing a usable network of data partners. Additionally, the Coordinating Center will need to demonstrate expertise in facilitating the secure transfer and hosting of data in a way that will protect patients and meet legal and regulatory requirements. Policies will be needed to ensure that any researcher that meets appropriate requirements will have access to the data network in accordance with the appropriate terms in the data use agreements and patient consent. As such, the Coordinating Center will need to have the resources to convene data partners and host stakeholder forums on data sharing and use policies that meet NMDES partner needs and protect patient privacy.

Research management and technical expertise

The Coordinating Center is a facilitator of research, not a research organization. However, it does need to ensure the appropriate scientific and ethics oversight of those activities facilitated through NMDES and be a catalyst for new methods development. This requires expertise on how epidemiological, safety, and effectiveness analyses are appropriately conducted, as well as an ability to understand trends and identify gaps in the current ecosystem to direct research priorities. The Coordinating Center will need to facilitate collaborative demonstration projects that will transparently evaluate the value of NMDES in general and the Coordinating Center in particular to stakeholders. This evaluation will need to include measures on

cost-effectiveness as well as metrics on the Coordinating Center's success in piloting data governance, navigating business relationships, and managing conflicts of interests.

Policy development and communication

The Coordinating Center will need the ability to actively promote and advocate for public polices and programmatic changes which advance NMDES development and capabilities. As such, demonstrated experience in effectively convening diverse stakeholders to advance the development and implementation of policies and programmatic changes is critical. A history of collaboration with federal partners to support appropriate policy advances would be useful.

Clear and transparent communication is one of the guiding system principles. Priorities for the Coordinating Center should include communicating key findings and research to build community awareness of its activities and engendering support through ongoing engagement and forums to solicit input from external experts and relevant stakeholders. The Coordinating Center should propose policies to ensure transparent communication and dissemination of relevant program and research activities, and the hosting organization should have experience at effectively convening forums of technical experts and stakeholders.

Proposed timeline for implementation

The Planning Board has recommended the following timeline in order to ensure NMDES can help CDRH meet its strategic goals.

Within six months: Once an organization has been selected to be the Coordinating Center, an interim executive director should be selected and in place within six months in order to provide day-to-day leadership.

Within one year: Within a year, a public nomination and selection process to appoint the Governing Board should be completed. Nominees will need to understand that the Board membership will require hands-on leadership for the general operations of the organization and that the Board will have legal and fiduciary responsibilities to NMDES. Members should be chosen based on their content expertise, ability to represent the perspectives of their stakeholder group, and commitment to provide the time and skills required to fulfill the Board's responsibilities. Members with a history of successful management of system implementation would be useful. The Planning Board envisions the Governing Board as a term-limited group of ten to fifteen members representing various stakeholder groups (patient/consumer advocates, physicians, hospitals, health plan representatives, manufacturers, health IT and methodologists). Members of relevant Government Agencies should also be on the Board (e.g., FDA, CMS, ONC, NIH, and AHRQ. The interim executive director should be subject to a vote of approval to become the permanent executive director within six months of the Governing Board's formation.

Also within the first year, the Coordinating Center will need to have proposed and initiated at least two demonstration projects based on a landscape survey of medical device evidence development methods and techniques and an assessment of stakeholder priorities and needs. Initial policies critical to the formation of the network of data partners will need to be in place, such as data curation and sharing, dissemination of results, and requirements for access of the network.

In addition, the Governing Board will need to rely on outside expertise at times to provide advice. Specific areas where expert input is likely to be needed include patient protection and privacy, science and

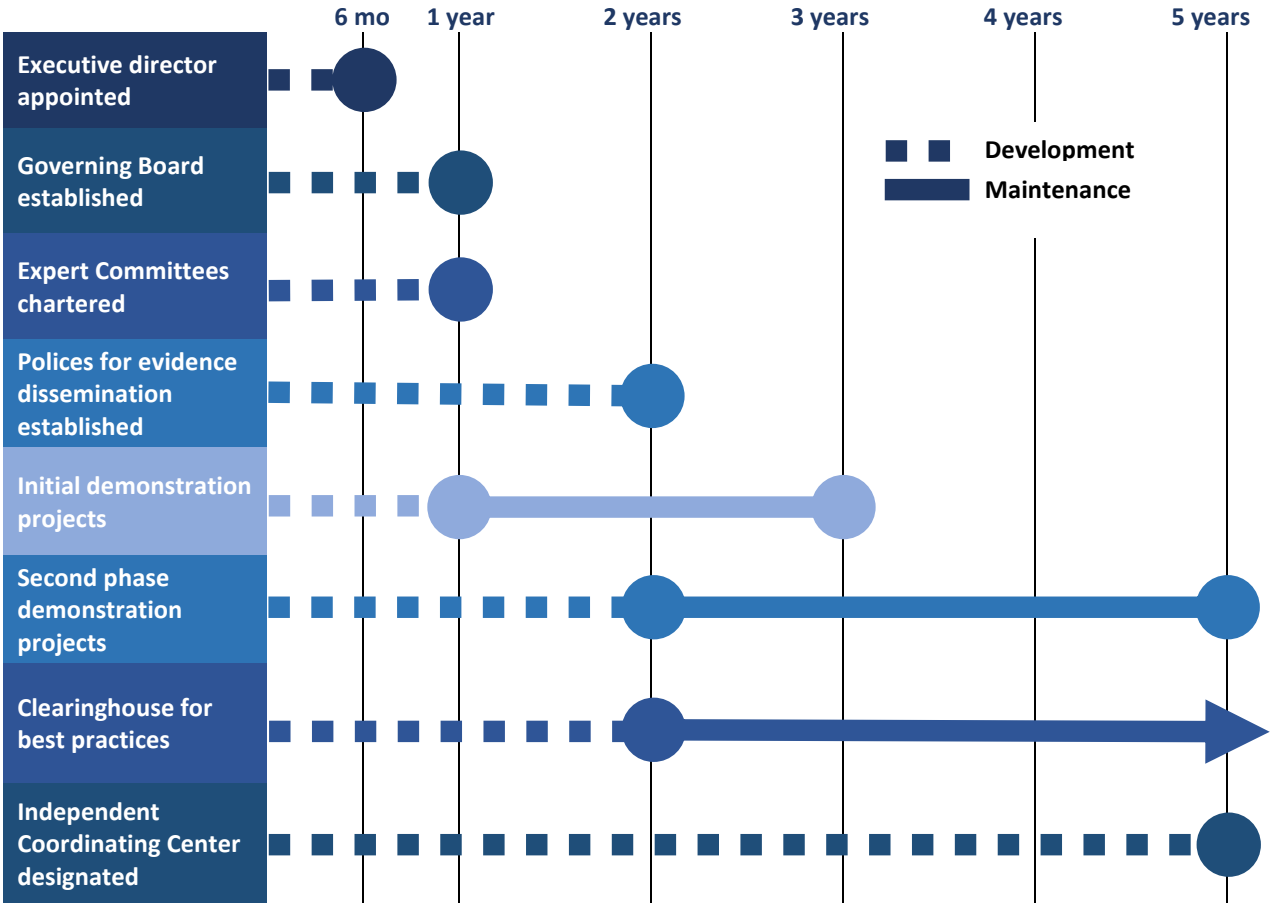
technology, and system sustainability. Expert committees in these areas should be chartered and convened within a year.

Within two years: After two years, the Coordinating Center should have created a publically accessible information clearinghouse of medical device evaluation activities, as well as have demonstrated expertise in coordinating and facilitating studies using NMDES. As part of this, the Coordinating Center should have publically accessible expert guidelines in place for evaluating signals and patient-focused processes for responsible dissemination of such information, as described previously in this paper.

At least two demonstration projects, one pertaining to safety surveillance and one focused on evidence development on device efficacy, should be completed by year 3. A second phase of demonstration projects should be started by year 2 and completed by year 5.

Within five years: Within five years, the Coordinating Center and the Governing Board should be transitioned into a financially stable, independent entity that is capable of scaling operations and managing the long-term sustainability of the system.

Figure B1. Timeline for Coordinating Center Activities



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[viii] NMDES principles are laid out in Chapter 2 of the Planning Board's 2015 report, *Strengthening Patient Care: Building an Effective National Medical Device Surveillance System*.