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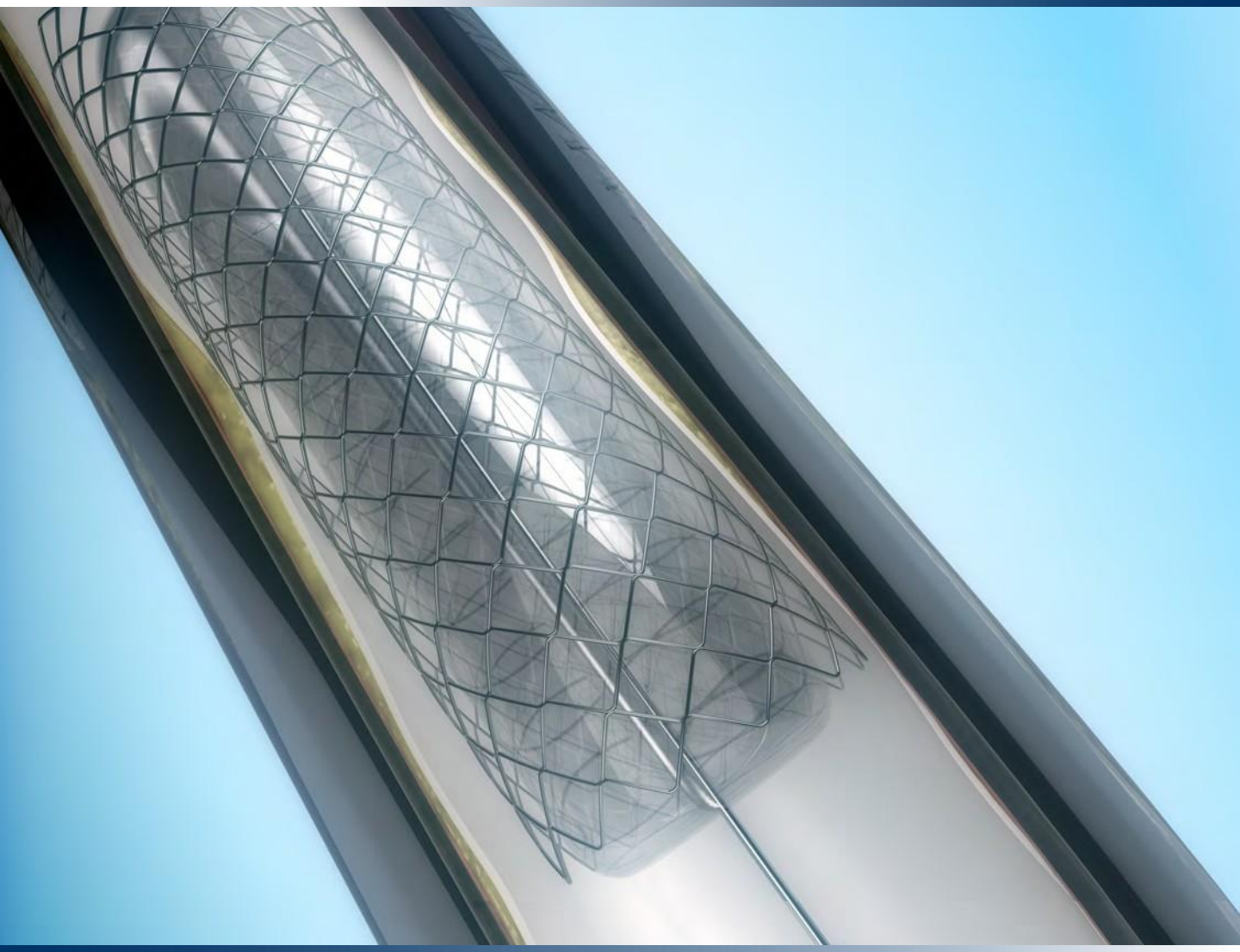

Strengthening Patient Care:

Building an Effective National Medical Device Surveillance System

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About the Engelberg Center for Health Care Reform at Brookings
Established in 2007, the Engelberg Center for Health Care Reform at Brookings is dedicated to providing practical solutions to achieve high-quality, innovative, affordable health care. To achieve its mission, the Center conducts research, develops policy recommendations, and provides technical expertise to test and evaluate innovative health care solutions.

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TABLE OF CONTENTS

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Executive Summary

Medical devices play a critical role in health care. Access to reliable and meaningful information about the safety, effectiveness, and quality of devices is essential to inform care and improve patient outcomes. While the Food and Drug Administration (FDA) has a public health mission to monitor the safety and effectiveness of devices, everyone has a vested interest in improving information about medical products. Patients and clinicians need information about devices to inform their clinical decisions. Organizations responsible for paying for care want to ensure that the products they cover lead to optimal patient outcomes. Manufacturers want timely feedback on device performance to support patient safety and drive innovation.

The Center for Devices and Radiologic Health (CDRH) at FDA put forth an action plan to strengthen the nation's postmarket surveillance system for medical devices in 2012. This plan was developed in response to concerns about the nation's ability to monitor the safety and effectiveness of medical devices, meet the challenges of supporting medical device innovation, and inform the evolving learning healthcare system. As part of this work, CDRH called for the creation of a multi-stakeholder Planning Board to identify the governance policies, priorities, and business models necessary to develop a sustainable national system for medical device postmarket surveillance. Under a cooperative agreement with CDRH, the Engelberg Center for Health Care Reform at the Brookings Institution convened the Planning Board in 2014. This report represents the Planning Board's long-term vision for a National Medical Device Postmarket Surveillance System (MDS) and recommended strategies for implementation.

Building a 21st Century Solution

The Planning Board's recommendations are focused on creating a collaborative system capable of supporting the development, regulation, and use of innovative medical devices. This system should be a component of the emerging national health information infrastructure. It should minimize burden by using data captured as an integral part of care to efficiently generate meaningful and reliable information about medical devices. The system needs to be driven by the need to improve public health and patient care. To accomplish these objectives, the Planning Board proposes the following mission:

*The **National Medical Device Postmarket Surveillance System (MDS)** supports 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 support this mission, MDS should be responsible for coordinating medical device postmarket evidence activities to ensure that there is a harmonized national approach focused on improving evidence and reducing burden. MDS should also build and facilitate access to a network of data partners that utilizes the emerging national health electronic information infrastructure to address medical- device specific questions.

The Planning Board does not envision MDS as a stand-alone system. Rather, MDS should build upon and coordinate with existing public and private sector programs to leverage their expertise and resources. For example, MDS should support Congress' mandate to include medical devices into the Sentinel Initiative, as well as coordinate with PCORI on their efforts to build a national research network.

MDS's primary function should be to provide better evidence on the benefits and risks of medical devices to enable active safety surveillance and more effective regulatory decision-making. The system should also seek to collaborate with other groups to support other high-priority evidence needs that

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could benefit from the same infrastructure, such as product tracking and utilization, clinical quality improvement, and economic analyses of medical device-related care.

The Planning Board recommends that MDS be implemented and managed by a multi-stakeholder public-private partnership (PPP) with sufficient authority and funding to support its activities. To support broad participation and transparency, the MDS PPP should be built around a set of organizational principles and data governance criteria focused on protecting patient privacy, meeting public health needs, balancing robust analysis and the burden of data collection, and building value for key stakeholders.

Recommended Implementation Approaches and Priorities

Years 1–2: Initiate an incubator project tasked to develop a 5-year implementation plan for MDS through fact-finding activities and pilot programs. The Board recommends that the incubator project should be initiated by FDA, adequately staffed and resourced, and guided by a multi-stakeholder group with relevant medical device experience.

Years 3–7: The second phase of work will focus on the MDS implementation plan produced by the incubator project. Once selected, the MDS PPP's leadership should set and oversee the system's strategic development priorities, begin to build and sustain broader stakeholder participation, oversee implementation of the organizational plan, and establish system performance measures. Some of the important challenges the MDS PPP must address during implementation include:

- Supporting a multi-pronged approach to ensure widespread adoption and use of Unique Device Identifications (UDI) in electronic health care data
- Minimizing the burden of data capture and sharing
- Developing policies to ensure the protection of patients and their privacy
- Building the capabilities to provide value to a broad group of stakeholders

The Planning Board believes that improved medical device surveillance is a public health and national priority and that the most effective way to address this priority is through the broad public-private partnership described in the report. However, without some initial seed funding and active FDA engagement, it will be difficult to assure the purpose and sustain the momentum necessary for other stakeholders to fully engage in the development of MDS.

The Planning Board recognizes that it is a challenging time for public funding of a national initiative on device surveillance, and that FDA does not currently have specific appropriations dedicated to support such an effort. While Congress enacted legislation in 2012 mandating FDA to expand the Sentinel system to include medical devices, it has not directed specific appropriations, user fees, or other resources to fund this work. The Planning Board believes that more explicit Congressional support is needed to create and sustain the needed infrastructure for a robust system of medical device surveillance in the United States.

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Acronyms and Abbreviations

AHRQ	Agency for Healthcare Research and Quality
AIRA	American Immunization Registry Association
AJRR	American Joint Replacement Registry
APCD	All-Payer Claims Database
AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
CDC	Centers for Disease Control and Prevention
CDRH	Center for Devices and Radiological Health
CER	Comparative Effectiveness Research
CMS	Centers for Medicare and Medicaid Services
CED	Coverage with Evidence Development
DELTA	Data Extraction and Longitudinal Trend Analysis
DEEDS	Data Elements for Emergency Department Systems
EAP	Expedited Access Program
EHR	Electronic Health Records
FDA	Food and Drug Administration
GUDID	Global Unique Device Identification Database
HIPAA	Health Insurance Portability and Accountability Act
HIT	Health Information Technology
IDE	Investigational Device Exemption
MAUDE	Manufacturer and User Facility Device Experience
MDEpiNET	Medical Device Epidemiology Network Initiative Public-Private Partnership
MDIC	Medical Device Innovation Consortium
MedSun	Medical Product Safety Network
MDR	Medical Device Reporting
MDS	National Medical Device Postmarket Surveillance System
NCQA	National Committee for Quality Assurance
NDC	National Drug Codes
NIH	National Institutes of Health
NCQA	National Committee for Quality Assurance
NVAC	National Vaccine Advisory Committee
OSHA	Occupational Safety & Health Administration
OCR	Office for Civil Rights
ONC	Office of the National Coordinator for Health Information Technology
OHRP	Office of Human Research Protections
PCI	Percutaneous Coronary Intervention
PCORI	Patient-Centered Outcomes Research Institute
PSO	Patient Safety Organization
PPP	Public Private Partnership
ROPR	Registry of Patient Registries
SCAAR	Swedish Coronary Angiography and Angioplasty Registry
TJC	The Joint Commission
TPLC	Total Product Life Cycle
TVT	Transcatheter Valve Therapy
UDI	Unique Device Identification

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CHAPTER 1

Planning Board Task and Background

All stakeholders have a vested interest in having access to more reliable and better information about the safety, effectiveness, and performance of medical devices than is currently available. Patients must be confident that devices involved in their care are reasonably safe and effective, and treats their condition with an optimal health outcome. Clinicians must have access to timely, accurate, and reliable information. Organizations responsible for paying for care want to ensure that the products they cover lead to optimal patient care and outcomes. Manufacturers want timely feedback on device performance to best support patient safety and optimal outcomes. Access to information about how devices perform in real world clinical settings can help medical device innovators develop products that are safe and effective, address unmet medical needs, improve outcomes, and create new business opportunities. Better information about medical products once they are on the market supports the public health, enhances patient safety, and improves the quality of care.

The U.S. Food and Drug Administration (FDA) is conducting and supporting a range of initiatives to enhance the nation's postmarket surveillance capabilities for medical devices. As part of this work, the Engelberg Center for Health Care Reform at the Brookings Institution convened the National Medical Device Postmarket Surveillance Planning Board (Planning Board) in 2014 under a cooperative agreement with FDA. The Planning Board was charged with developing a set of long-term principles and priorities for a National Medical Device Postmarket Surveillance System (MDS). The tasks included identifying potential governance and business models that address legal and privacy considerations, system financing and stability, mechanisms to support the appropriate use of data, and policies to ensure system transparency, as well as providing recommendations about how the system could be maximally utilized to reflect the needs and capabilities of medical device stakeholders and groups involved in creating and using postmarket evidence.

The Planning Board membership includes representation from a broad array of stakeholder groups and areas of expertise such as patients, clinicians, hospital organizations, hospitals, health plans, regulators, and government agencies, as well as methodologists, the medical device industry, and academic researchers. For a description of the planning board selection process and member biographies, see Appendix A.

I. Overview of Medical Device Life Cycle Regulation

The primary mission of FDA's Center for Devices and Radiological Health (CDRH) is to protect and promote public health by assuring that patients and providers have timely access to safe, effective, and high-quality medical devices and radiation-emitting products.[1] A critical part of achieving this mission is weighing evidence of the potential benefits against the potential risks associated with medical devices before they are cleared or approved by CDRH to be marketed in the U.S. Medical devices are assigned to one of three regulatory classes (Class I, Class II, or Class III) based on the level of control necessary to assure the safety and effectiveness of the device.[2] Class I devices generally pose the lowest risk to the user and Class III devices pose the highest risk. Once available in clinical practice, these devices are generally used in broader patient populations, by more diverse groups of clinicians, and potentially in different ways than were previously studied. It is therefore essential to CDRH's mission to have the capability to collect, analyze, and act on this new information about the safety and effectiveness of

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medical devices. Developing systematic evidence on medical devices has been challenging however, and a series of high-profile adverse events related to medical devices in recent years[3,4,5] has raised questions about CDRH's ability to monitor and act on potentially important safety concerns.[6,7]

Significant progress has been made in the last decade across the health care system to capture electronic clinical and patient-reported information as a part of routine care. Recognizing that this information could be leveraged to develop a more robust and active system to monitor the safety and effectiveness evidence of medical products, CDRH conducted an internal review of its postmarket safety surveillance system and capabilities in 2012.[8] This review outlined the Agency's vision for a national active surveillance system with the ability to identify and evaluate potential safety signals in near real- time, enable systematic assessments of the benefits and risks of medical devices throughout the product life cycle, and reduce the burden and cost of postmarket surveillance, as well as to facilitate the clearance and approval of novel devices and new uses for existing devices. CDRH proposed four action steps that, in combination, would create the foundation for the system. These steps included: 1) establishment of a unique device identification (UDI) system and promoting UDI adoption and integration into electronic health information; 2) development of national and international registries for selected devices; 3) modernization of adverse event reporting and analysis; and 4) development and application of new methods for evidence generation, synthesis, and appraisal.[8]

These recommendations also support the second part of CDRH's mission to facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways. The design and conduct of the clinical studies required for premarket approval of higher-risk devices are often time-consuming and costly.[a] While the purpose of this process is to ensure that these devices are both reasonably safe and effective, as required by law, it can also have the unintended consequence of delaying access to life-saving medical advances.[b] Beyond modernizing adverse event reporting, a postmarket surveillance system for medical devices could also leverage real-world clinical data to support more efficient clinical trials and better evidence development for regulatory decision-making, including ongoing benefit and risk assessments, and expansion of product indications.

CDRH has long recognized product development and use in the context of the Total Product Life Cycle (TPLC).[9] Currently, CDRH envisions a more robust postmarket surveillance system to facilitate device innovation and patient access to technologies, reduce postmarket data collection requirements of device firms, and provide more robust benefit-risk profiles of devices so that providers and patients can make better-informed health care decisions. CDRH has taken a number of steps to create a more integrated pre- and postmarket review process for medical devices with the goal of making the TPLC process safer, more efficient, and more productive. Several relevant guidances have been issued over the past few years. FDA issued guidance, in 2012, on the principal factors that it considers when making benefit-risk determination during the premarket review for devices subject to premarket approval applications or de novo classification.[10] In 2013, FDA issued guidance on Investigational Device Exemption (IDE) applications for early feasibility studies of significant risk devices.[11] Refinement of high-

[a] The regulatory requirements for Class II and Class III devices differ based on the level of risk and similarity. The premarket approval process for Class III devices (the highest risk class) requires a comprehensive safety evaluation, particularly for riskier and newer medical devices.

[b] Most devices are cleared as substantially equivalent through the 510(k) process

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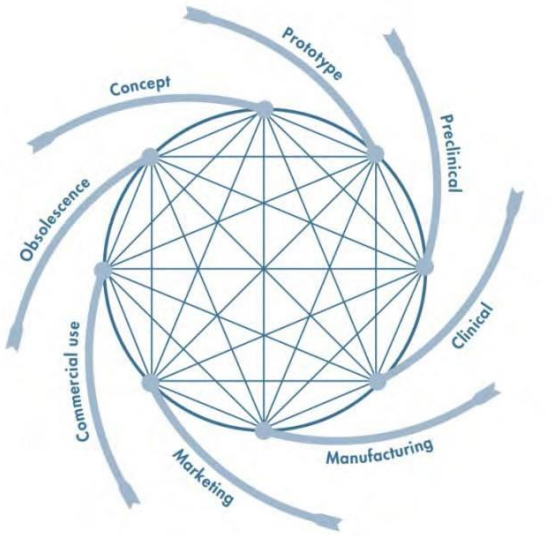
risk devices early in the design phase and robust surveillance in the postmarket setting could ease the burden currently associated with the premarket approval process and mitigate postmarket risks.

CDRH has also issued new guidance on balancing pre- and postmarket data collection during review of premarket approval applications.[12] The guidance highlights the necessity for extensive data collection to support the premarket approval process, data needs that could potentially be addressed through more timely and complete postmarket data collection. Recent actions, such as the proposed Expedited Access Program (EAP), are also part of ongoing efforts by CDRH to shift to postmarket data collection to facilitate medical device innovation.[13] This shift does not mean FDA accepts less evidence of safety and effectiveness but is an acknowledgement that postmarket data better reflects the real world.[13] Achieving this balance has been central to CDRH's 2014–2015 strategic priorities.

Figure 1: FDA Total Product Life Cycle



While these steps seek to better balance pre- and postmarket data collection, limitations of current postmarket surveillance systems mean that regulatory attention and resources remain largely focused on the premarket approval process for ensuring the reasonable safety and effectiveness of medical devices and reducing the risk of adverse outcomes. CDRH has the authority, however, to develop and rely on postmarket activities that may support TPLC through FDA-mandated requirements for industry such as post-approval studies (PAS)[c] and Section 522 studies.[d] However, reliable postmarket surveillance is often not feasible, at least at a sustainable cost, because the infrastructure for conducting such studies for medical devices has generally not been developed. Where postmarket studies are required for particular products, they are often expensive, one-time studies that use infrastructure, methods, and systems that are not scalable or reusable.[8] FDA is also tasked with providing consumers, patients, their

[c] The CDRH Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application, protocol development product (PDP) application, or humanitarian device exemption (HDE) application.

[d] Section 522 of the Federal Food, Drug and Cosmetic Act (the act) gives FDA the authority to require a manufacturer to conduct postmarket surveillance of a class II or class III device that meets any of the following criteria: its failure would be reasonably likely to have serious adverse health consequences; it is expected to have significant use in pediatric populations; it is intended to be implanted in the body for more than one year; or it is intended to be a life-sustaining or life-supporting device used outside a device-user facility.

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caregivers, and providers with understandable and accessible science-based information about the medical devices it oversees. Up-to-date and relevant information on medical products and their use and impacts in particular sub-groups of patients could come from data from actual medical practice. But current surveillance generally lacks the ability to effectively evaluate medical device data from real-world practice and to make such science-based information available to the public.

Current FDA Postmarket Tools and Limitations

CDRH has the authority to issue mandatory recalls, withdraw approval of devices, and reclassify devices whose risks are proven to be higher than originally anticipated.[14] The Agency can also follow up on potential concerns by inspecting firms, which includes assessing complaint files, recall-related information, in-process testing and results, and information on suppliers and manufacturers.[15] However, the ability of FDA to use these authorities effectively is limited by the quality and timeliness of the postmarket evidence that it is able to use as a basis for regulatory actions. CDRH's postmarket authorities for obtaining evidence on the safety and effectiveness of marketed medical typically fall within two primary categories—adverse event reporting and mandated industry postmarket studies.

Two of the tools used by CDRH to capture adverse event reports are Medical Device Reporting (MDR) and the Medical Product Safety Network (MedSun) programs.[16] MDR is a postmarket surveillance tool intended to collect reports of device-related adverse events, use errors, product quality issues, and device failures. CDRH uses this information to identify potential safety signals, monitor device performance, and contribute to benefit-risk assessments of these products. Device manufacturers and importers are required to report information that leads them to believe that one of their devices has caused or contributed to an adverse event (death, serious injury, or malfunction) within 30 days of receiving that information. User facilities (such as hospitals and nursing homes) are also required to report device-related deaths and serious injuries. CDRH encourages, but cannot require, health care professionals, patients, caregivers, and consumers to submit voluntary reports about serious adverse events and product problems that may be associated with a medical device.[17] Reports from health care professionals represent a significantly small proportion of MDRs submitted directly to CDRH. These reports do not represent "active" data collection and submission, but are reflective of voluntary, "passive," surveillance.

Manufacturers submit more than one million adverse event reports annually to CDRH.[18] Of these, there are more than 50,000 reports of serious adverse events resulting in hospitalization or other injury associated with the use of medical devices, including more than 3,000 potential deaths per year.[18a] There are a variety of reasons why these reports may not be a reasonable or sufficient basis for recalls or other regulatory actions. Lack of exposure data (the denominator)—population-based and longitudinal device-specific information in these "passive" reports—may at times, inhibit CDRH's ability to interpret and act on adverse event reports. When adverse events are reported, however, CDRH may ask the manufacturer to follow up to obtain additional information about the device and/or event before making a determination.

CDRH also partners with a network of approximately 250 health care facilities under the MedSun program to collect real-world information about device problems in hospitals.[19] These facilities devote considerable resources to collect high-quality reports, participate in surveys, assess recall effectiveness, and conduct educational forums. Reports captured in MedSun are typically more reliable and higher quality, but they primarily include Class II devices with only a small number of Class III devices.[20]

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Both MDR and MedSun reports are stored in the Manufacturer and User Facility Device Experience (MAUDE) database.[21] Although electronic reporting of adverse events enhances timeliness, quality, and efficiency of analysis, only 70% of MDRs are currently submitted electronically.[8,e] Technology limitations and the number of reports overwhelm CDRH's surveillance resources, increasing the risk of data error and misclassification. Incomplete reporting often inhibits safety signal identification, and subsequent investigation and actions by manufacturers and FDA.

Larger longitudinal databases have begun to emerge from payer systems, procedure registries used for quality improvement and other research studies, and electronic record systems used in care delivery. CDRH frequently relies on such third party data, and their further development holds increasing promise for the future. We describe the potential for enhanced use of these systems later in our report. However, such systems are presently limited in many ways, including the absence of a UDI to enable particular devices to be reliably connected to patients and outcomes, inconsistent data standards, barriers to data sharing and consistent analysis, and the general lack of an infrastructure to support their use for device surveillance.

As noted above, FDA also has the authority to mandate that manufacturers conduct postmarket studies for some devices. FDA may order a post-approval study as a condition of approval for a device approved under a PMA order. Typically, post-approval studies are used to assess device safety, effectiveness, and/or reliability, including longer-term, real-world device performance.[8] FDA may also order a manufacturer of certain Class II or Class III devices to conduct a "522" postmarket surveillance study for devices cleared through the 510k process or approved under a PMA. 522 studies vary widely and may include non-clinical device testing, analysis of existing clinical databases, observational studies, and, rarely, randomized controlled trials.[22] However, because there is no general framework or infrastructure available for conducting these studies, they have often been difficult to implement and complete reliably. 522 studies have been criticized for inconsistencies in design, the lack of oversight, timeliness of reporting findings, and how the information is eventually used.[23,f] A key challenge in conducting these studies is a lack of incentives for clinicians and patients to participate, because they represent already marketed devices and an additional reporting burden and other requirements on top of their usual practice. As a result, FDA and manufacturers are exploring registry-based surveillance as an alternative.

In some cases, patients and providers in the U.S. have had to rely on adverse events identified through foreign surveillance systems. For example, the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and the National Joint Registry for England and Wales (National Joint Registry) were the first to publish peer-reviewed literature on the increased failure rates of metal-on-metal hip joints compared with other materials.[24,25] Using data collected from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR), a landmark study found that drug-eluting stents were associated with an increased risk of death as compared with bare-metal stents.[26] In both cases, data collected by these registries identified serious safety concerns much sooner than in the U.S.[27,28] In addition, data collected in the AOANJRR found that many new products did not improve health outcomes compared to older devices, and that patients and taxpayer-financed health care programs were paying a high cost for these expensive devices with marginal returns.[29] This example highlights that postmarket data can be used to not only monitor the safety of devices, but also to better understand and measure device innovation and cost effectiveness.

[e] In February 2014, FDA issued Electronic Medical Device Reporting (eMDR) that requires manufacturers to submit MDRs to FDA in an electronic format. FDA anticipates electronic reporting of MDRs will account for 95 percent of all reports submitted.
[f] FDA has oversight responsibility for the design of 522 studies.

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Building Blocks for Better Medical Device Surveillance

There are several existing and emerging efforts that are expected to significantly enhance CDRH's ability to conduct postmarket surveillance of medical devices and the development of a learning health care system. Throughout this report, the Planning Board identifies examples of ongoing efforts and how we can learn from their experiences and build upon their momentum (see Table 1.1). For example, CDRH's Medical Device Epidemiology Network Initiative Public-Private Partnership (MDEpiNet) is a collaborative program through which CDRH intends to develop new and more efficient methods and means to study medical devices, enhancing FDA's ability to better understand the safety and effectiveness of medical devices after they are marketed.[30] As part of MDEpiNet's work, CDRH has also established the National Medical Device Registry Task Force to address implementation of registries in postmarket surveillance.[8] The Task Force has been charged to develop strategies for the use of registries to support both premarket approval/clearance and postmarket indication extensions in labeling. The Task Force is also charged to identify existing registries that may contribute to a postmarket surveillance system, prioritize medical types for the establishment of a longitudinal registry, and determine successful registry governance and data quality best practices. The Task Force's report is expected to be released in late spring 2015. There are a number of other efforts also making progress toward improving the ability of registries to capture clinical information on device utilization and performance, most of which has focused on high-priority therapeutic areas such as high-risk cardiovascular and orthopaedic devices.[31,32,33]

Another potentially important building block is FDA's Sentinel Initiative, a national electronic system to monitor the safety of FDA-regulated medical products so far applied primarily to help assess the safety of drugs and biologics.[34] FDA launched the Mini-Sentinel pilot project; this has now grown into the full Sentinel Initiative, which incorporates 18 collaborating institutions or data partners and already covers nearly 180 million individuals. To date, Sentinel has not focused on medical devices due to the absence of UDIs. However, once UDIs are implemented, the system could potentially be a much richer source of data relevant to medical device surveillance. Other public-private partnerships are also working to address gaps in postmarket surveillance of medical devices and are engaged in a wide array of activities such as methodology research, international registry harmonization, patient-reported outcomes tools, UDI capture pilot projects, and medical device cyber security initiatives.[30,35,36]

Beyond safety surveillance, there are a number of other efforts underway to develop large-scale or national systems capable of generating reliable information to inform a learning health system. The Centers for Medicare and Medicaid Services (CMS),[37] the National Institutes of Health (NIH),[38] the Agency for Healthcare Research and Quality (AHRQ),[39] and the Office of the National Coordinator for Health Information Technology (ONC)[40] are all actively engaged in efforts to facilitate the development of programs, policies, and systems for generating evidence on patient care, outcomes, and appropriate health IT systems. The All-Payer Claims Database (APCD) Council is working with several states to develop and implement state-based APCDs to inform state-level health policy issues such as health insurance exchanges and state agency reform efforts.[41] Additionally, the Patient-Centered Outcomes Research Institute (PCORI) launched PCORnet in 2013 to begin development of a national collaborative research infrastructure focused on comparative effectiveness research.[42] The National Quality Registry Network® serves as a hub to promote the use of registries and to disseminate leading practices among registry stakeholders.[43]

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Table 1.1: Promising Existing and Emerging Efforts in Postmarket Evidence Development

	Program	Activities	Data Elements	Sponsors
Medical Device-Focused Efforts	MDEpiNet	• Development of methodological and analytical tools • Development of large-scale research collaborations • Registry Task Force	• UDI integration into provider systems (e.g., Mercy pilot) • International registry standards (e.g., ICOR)	• FDA-CDRH • Duke Clinical Research Institute • Harvard-HCP • Cornell
	Medical Device Registries	• Active safety surveillance (e.g., DELTA system) • Support regulatory decision-making, such as condition of approval and 522 studies and CED (e.g., TVT Registry) • Quality improvement/ performance reporting, such as PQRS/HQRP (e.g., AJRR, NCDR)	• Clinical data only • Clinical and device data (e.g., NCDR) • Clinical and device data, including attributes (e.g., ICOR)	• CMS • NIH • FDA-CDRH • AHRQ • VA • Medical Societies • Patient Advocacy Orgs
	MDIC	• Clinical trials innovation and reform • Computer modeling and simulation • Patient-centered benefit-risk assessment	• Patient-reported outcomes	• Manufacturers • Patient Advocacy Orgs • FDA-CDRH
Broader Evidence Development Efforts	Mini-Sentinel	• Safety surveillance of medical products	• Claims-based Common Data Model • Limited Electronic Health Record (EHR) data	• FDA (via Congress)
	IMEDS	• Development and evaluation of surveillance methods (e.g., PROMPT assessment) • IMEDS Open Lab • Piloting access to the Sentinel System by non-FDA organizations	• Open access to de-identified claims and EHR data • Claims-based Common Data Model • Limited EHR data	• Reagan-Udall Foundation • FDA • Manufacturers
	Disease-specific Registries	• Quality improvement • Comparative effectiveness research • Clinical decision support • Engaging patients • E.g., SUPREME-DM, ImproveCareNow	• Administrative claims • EHRs • Patient-reported outcomes	• AHRQ • PCORI • NIH • FDA
	Distributed Research Networks	• Patient-centered clinical trials (e.g., HCS NIH Collaboratory, PCORnet) • Patient-centered comparative effectiveness and outcomes research (e.g., SCANNER, PCORnet)	• EHRs • Patient-reported outcomes	• PCORI (via Congress) • NIH • AHRQ

While all of these efforts are supporting the development of better evidence, their uses for medical devices are limited. First, UDIs are not currently captured in most electronic data systems. Second, while many of these systems are moving toward closer integration with electronic data developed and used

for patient care, medical device initiatives still require considerable additional data input and management, which significantly increases costs. Third, most of these initiatives require their own independent funding and the incentives or business case for supporting them has not yet been made clear for many of the key stakeholders.

II. Planning Board's Approach to Envisioning the Future National Medical Device Surveillance System

The Planning Board was tasked with envisioning a MDS with the capability of accurately and systematically evaluating potential medical device safety signals in near real-time, measuring the benefit-risk profile of devices throughout their life cycle, and developing meaningful information to support pre- and postmarket regulatory decision-making. In this task, the Board sought to envision a long-term system that would meet the needs of all stakeholders to assess the benefits and risks of a device throughout its lifecycle in a transparent, timely, accurate, and systematic manner. The Board also believed that MDS must facilitate the improvement of evidence-generating activities more broadly from the American health care system.

Assumptions

The Planning Board identified a set of assumptions about technical, programmatic, and policy changes that may take place over the next decade regarding health care delivery and assessment. The assumptions were based on the Planning Board members' expertise and understanding of the health care environment, and the types of changes to the national health care infrastructure and capabilities currently underway. These assumptions about the possible future health care environment were used to support the participants' long-term vision of a national medical device postmarket surveillance system.

The Planning Board believes that movement is underway toward a learning health care system that will permit much more detailed assessment of key aspects of the health care system on an ongoing basis. The evidence generated from these assessments will be used to modify practice, inform policy development, and continually drive improvement.[44] A central component of a learning health care system is the move to patient-centered data collection and analysis, necessary to enable health care to be more personalized to individuals and their needs and to capture patients' perspectives to inform and improve the ongoing delivery of services.

The Planning Board also assumes that the shift toward more personalized care will incentivize the development of better evidence. Payments to providers, insurance benefit design, and patients' decisions about medical care services will increasingly be tied to results. Patients and purchasers will seek out health care organizations that deliver higher-quality, more efficient care. These reimbursement and financing shifts will help create a clearer business case for longitudinal data collection, decision support systems, public information on devices, and other applications to enable better medical device surveillance. In particular, measures of patient outcomes and quality of care will increasingly be collected, analyzed, and used to inform programmatic and policy changes, including medical device surveillance. Importantly, these measures will increasingly rely on real-world data collected as part of routine care.

Similarly, and in response to these trends, the Planning Board assumes that, within a decade, health IT will have matured to the point that 1) UDIs will be routinely collected within electronic health information as an integral part of care, 2) EHRs including UDIs will be widely used across health care

providers and settings, and 3) different health information systems will have interoperable capabilities to allow key data on individual patients to be linked. These will enable much more sophisticated medical device surveillance.

In describing a future MDS, the Planning Board also adopted a broad definition of medical device innovation as a modification or change that improves the quality of, efficiency of, or access to safe health care products.[7] This is consistent with the life-cycle view of medical devices described earlier; indeed, with better opportunities emerging for "combination" medical products and products more individualized to particular patients, such ongoing progress involving medical devices on the market may be an increasingly important part of medical device innovation.

Report Scope and Limitations

The Planning Board decided to broadly frame the long-term vision for MDS's core capabilities, principles and key components given the distant horizon of the task (about 10 to15 years in the future), uncertainty about future changes to the health environment, and the ever-evolving nature of technology. The report is designed to propose the characteristics of a viable long-term system in order to spur discussion, debate and refinement, and progress. The Planning Board has made a number of recommendations about potential approaches to addressing some of the current challenges impeding progress toward the long-term goals of MDS. These recommendations focus on the types of changes that need to take place in the generation, analysis, and application of medical device safety and effectiveness information.

The Planning Board also recognizes there are limitations to the scope of the task and what the report can address. Where possible, the report refers to other initiatives working on specific issues related to the Board's work that are clearly relevant to achieving the broad vision outlined here, such as the activities of MDEpiNet, the Medical Device Registry Task Force, Sentinel, and the MDIC.

Finally, the Planning Board recognizes that, as of today, the key assumptions underlying a viable MDS may appear idealistic and distant. However, by providing a clear vision of how MDS will be part of such a future health care system, we aim to provide momentum to accelerate progress to get there. In Chapter 4, we return to a more detailed discussion of our recommendations for getting from here to there, including steps that can help make the assumptions become a reality more quickly.

III. Creating Value for Stakeholders: Key Features of the National Medical Device Surveillance System

In order for the MDS to succeed, it must develop and maintain the support of all major stakeholders. The Planning Board recognizes that many of their recommendations will ask various groups to implement changes that are challenging and may not appear to add value to their work in the short-term. Building the momentum necessary for these changes will necessitate the stakeholders who are already engaged in medical device postmarket surveillance activities actively collaborating to mitigate burden and demonstrate value.

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Patients

Improving care and outcomes for patients should be at the center of efforts to improve medical device surveillance. All other stakeholder concerns relate back to improving patient well-being. Devices connected to, implanted in, and used by patients have immediate, intimate, and acute impacts designed to improve the health status of the patient served. However, safety and performance issues can derail these positive outcomes as well as overall confidence in the health care system. Identifying both safety problems and additional benefits of devices in a timely manner can accelerate product improvements, interventions, and recalls. Providing better device surveillance information to patients will give them a better understanding of the devices they use, help them make better decisions, drive further improvements in care, and advance patient ability to be engaged and proactive in their health care.

Engaging patients and consumers is a critical component of the national system; they need to be an integral part of the steering and vision of the MDS. This will ensure that MDS is focused on patient needs, improving the quality and types of information collected, and how best to disseminate and communicate information about the safety, effectiveness, and performance of medical devices. Patients and consumers should feel confident their health information is used appropriately and is secure in the process of supporting a system for medical device safety. MDS will be built using information from patient experience with medical devices from a range of data sources, including EHRs, payer claims data, clinical registries, and patients themselves. Incorporating patient-generated health information, including patient-reported outcomes, will broaden the medical device data available for analysis within the system. This should support better data for the public, optimal care personalized to patient needs and perspectives, regulatory decision-making, and improvement of device performance.

Patients and consumers should be ensured access to timely and reliable information on the devices they have received or may receive to inform their decisions, increase confidence in device safety, and be confident that best practices are in place to detect and respond to safety issues should they arise. Earlier access to new and novel medical technology is an additional potential benefit for patients and consumers. Patient advocacy and support organizations seeking to address critical health-related questions may also contribute to and benefit from participation in MDS.

Clinicians

Clinicians are committed to providing health services and making health care decisions with their patients to achieve the best possible outcomes of care based on the patients' needs and goals. Clinicians are the direct link with patients to the health care system and have the potential to be an important contributor of information to the system. In return for reporting clinical information, clinicians can receive population-level data on procedures and devices (e.g., safety, quality, comparative effectiveness). Clinicians need this information to ensure the quality of care they provide and adjust clinical practice. Clinicians are also dependent upon premarket information about the medical devices that they use in clinical practice. Access to more standardized and comprehensive information about the safety and effectiveness of medical devices could assist clinicians in making more evidence-based decisions, and facilitate shared decision-making with patients. Additionally, more robust postmarket information can trigger clinical decision support to select the device or monitoring of the device.

A reliable device surveillance system would support clinicians by identifying and sharing information about potential problems earlier, reducing the number of patients exposed to the device, and/or notifying those affected earlier so that actions can be taken to mitigate the risks for those already exposed. For instance, information from MDS could be incorporated in clinical care support software and EHRs to quickly inform clinicians about recalled devices.

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While clinicians often have access to important information, gathering that information at the point of care comes at a considerable cost. Moving to systems that collect more complete information in a standardized electronic format has additional costs related to technology and staff resources. The size of these costs, which are high for most practices today, impacts the feasibility of obtaining needed surveillance data from clinical practice. It is also challenging to get the type of data needed to support postmarket evidence development (UDI, clinical outcomes, and patient-reported outcomes).

While it is plausible for clinicians to buy in to the value of the information potentially created by MDS, without incentives, the long-term sustainability of the system is questionable if reporting data is a substantial burden. As the nation moves toward a learning health system, there are various mechanisms that may provide financial incentives for clinicians to contribute data. In particular, there are alternative payment models emerging which shift reimbursement to focus on patient outcomes (e.g., ACOs) rather than on volume-based services (e.g., fee-for-service). Even with these programs, it will be essential to integrate data reporting into provider workflow and to support as much automatic data capture as possible instead of relying only on provider data entry in order to obtain widespread and sustainable clinician buy-in and participation. Another incentive for clinicians is the ability to receive the generated information in an easy-to-use format.

Health Care Organizations

Hospitals, health systems, and other health care provider organizations are focused on providing quality, safe, patient-centered, and cost-efficient care. A key factor for these types of organizations is value. Medical devices are an integral part of patient care, yet availability of comprehensive evidence on performance and comparative effectiveness; comprehensive and timely information informing recalls and safety alerts; and transparency of product utilization and national benchmarking data is lacking in the current system. Outcomes of this impact both clinical and operational decision-making in provider organizations. Hospitals procure and have available medical devices for use in patient care. Quality and safety is central to these choices, but cost is also an essential consideration as medical supply management and procurement is the second-highest operational expense for provider organizations.

Desired is a solid evidence base to inform device choice, recall and safety alert information based on timely and comprehensive data made available as quickly as possible, and availability of national benchmarking data on device utilization. All of this would support the ability of provider organizations to better assess device choices for clinical use; more effectively inform the balance of clinical and cost decisions; and support greater collaboration, data assessment, and analysis between clinical and operational teams.

Challenging for provider organizations is their ability to comprehensively assess device performance, comparative effectiveness, and cost. For many device types and categories, there are gaps in the clinical literature on performance and comparative effectiveness. Comprehensive national-level data on utilization and cost to be used for benchmarking is generally not available.

A robust national medical device surveillance system would help fill this gap in availability of medical device data and support provider organizations in meeting these desired goals. Greater availability of performance and comparative effectiveness data would support: decision-making through technology assessment and value analysis processes; contracting; and development of clinical guidelines and protocols involving devices. Through making data more readily available, comprehensive and timely safety surveillance data would better inform recall management. Quicker removal of devices from the

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market and the health care delivery site should logically reduce the number of impacted patients. Hospitals could have greater confidence that more timely information would be made available on problematic devices, thus supporting quality care, comparative effectiveness research, and better population health. National data on device utilization would provide a benchmark for which provider organizations could compare themselves. This, coupled with clinical evidence and outcomes data on medical devices, would support provider organizations' ability to make optimal decisions for quality, safe, patient-centered, and cost-effective care.

Medical Device Industry

Manufacturers work to produce quality products that meet the needs of patients and generate revenue that allow for continued innovation. They are also held accountable by not only FDA and foreign regulators, but also by the healthcare system and patients they serve for the safety and effectiveness of their products. Hence, manufacturers have a vested interest in modern systems for systematic and efficient evidence development on patient outcomes.

Manufacturers are subject to various CDRH postmarket reporting requirements. While these requirements are intended to monitor the safety of products once they are on the market, as noted before, there are significant concerns about their capability to identify and evaluate potential safety signals in a timely and reliable manner. In addition, current postmarket requirements, including MDR and mandated postmarket studies, are burdensome and costly to medical device manufacturers. While manufacturers would benefit from a more efficient and effective system, they are appropriately concerned that any new system would add burden to their current reporting requirements. In order for FDA to either replace or reduce current requirements, the new system would need to demonstrate that it could provide a more effective and reliable mechanism to monitor safety and provide evidence about effectiveness.

An additional value of MDS could be in supporting more effective recall management if a safety issue is detected. Manufacturers are responsible for managing any product recalls or corrective actions, and they track Class II and III devices through their own supply chain management systems. They depend upon this information to facilitate notifications and recalls in case it has been determined that their devices present serious risk to public health. At present, many device manufacturers have limited ability to track patients who have had their devices implanted. As envisioned, a new system with UDIs integrated into the electronic health information (EHRs or claims data) and insurance claims system could more effectively determine a patient's contact information as need arises.

Beyond safety surveillance, this system has the potential to support regulatory and reimbursement decisions about currently marketed products, including indication expansion/refinement and product innovation throughout the total product life cycle of the device. The new system could provide the infrastructure for longitudinal clinical studies in real-world settings to help assess products' benefits and risks, evaluate outcomes in different populations, and identify potential product refinements.

The national system has the potential to support policy decisions as well as to provide critical information that manufacturers can use themselves, or in collaboration with clinical research organizations, to pursue investigations about the value of their devices, in particular settings beyond the MDS's primary functions. For example, they may be interested in examining safety and effectiveness in various patient subgroups of interest or in comparing treatment risks and benefits of medical devices compared to pharmacotherapy, or various delivery methods of a particular drug.

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Payers and Purchasers

Health insurance plans use claims data to reimburse providers and clinicians for care provided to patients, often acting on behalf of employers and other purchasers who are under strong pressure to reduce health care costs while providing high-quality care. Consequently, payers and providers are very supportive of efforts to improve device safety and quality. Payers also routinely use their claims and administrative data for quality improvement within their network to identify opportunities to improve care and reduce system waste, including by developing information on how to use devices more effectively. In addition, payers are facing growing demands for reporting quality, safety, outcomes, and cost information to consumers.

The information increasingly used in these payer and purchaser activities also represents a critical set of data to support the national postmarket system to better monitor medical devices. Payers would benefit from more effective safety monitoring, earlier identification of device performance and complications, and support recall management. However, beyond improved safety information, participating in the national system may benefit payers by providing them with additional information to supplement their data networks and resources. Payers vary widely in size and capabilities. Smaller plans have less ability to evaluate the efficacy and safety of interventions and even large plans have difficulty in evaluating interventions that occur infrequently due to the small numbers involved.

MDS could enable individual payers through the use of UDIs to link their data with additional clinical detail from medical device registries, clinical data systems, and other data sources for the purposes of device surveillance. Access to data within MDS could enable payers to use national and regional information to evaluate and guide clinical policy development, performance and quality tracking, and support value-based payment models. Access to data sets that are larger than those acquired directly by payers is important in evaluating the safety and efficacy of individual devices, especially relatively new ones, as the number of treated patients may be too small to draw meaningful statistical conclusions.

A national system has the potential to support more efficient research for coverage decisions by payers, such as the CMS Coverage with Evidence Development (CED) program. In addition, the use of recognized national data sets by manufacturers could enhance the data that they present to health plans, including cost and cost-effectiveness data.

Organizations that collect information about payers and health care quality may also find value in MDS. For example, the National Committee for Quality Assurance (NCQA) collects and reports performance measurement information on managed care organizations.[45] Access to the national system's data can support their efforts to inform purchasing decisions.

Public Sector

The MDS can be of significant value to the public sector, for all of the reasons we have described plus the capacity for supporting other reinforcing public policy goals. The MDS could support the research activities of public health authorities and other public sector organizations, such as the NIH, CMS, and AHRQ, and is aligned with the mission of ONC.

The NIH supports development, design, testing, clinical evaluation, and implementation of medical devices as part of its mission.[38] NIH-supported device development capitalizes on the successive movement of scientific discovery from the molecular and physiological basis of health and disease to clinical application and use. Institutes and Centers within NIH support device development in cardiology, orthopaedics, ophthalmology, neurology, pediatrics, and other areas. A flexible registry-based system

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could provide rapid access to clinical populations to accelerate proof of concept trials and to test expanded indications for existing devices. Registry data could also provide the basis for hypothesis generation and support scientific investigation. An enhanced postmarket surveillance system could also facilitate research to identify and ameliorate the root causes of adverse events and device malfunctions.

CMS is currently engaged in various activities focused on developing and implementing additional evidence to support the evaluation of quality in health care services, clinical effectiveness, and clinical outcomes. CMS's Quality Initiatives encourage clinicians and provider organizations to report on quality metrics of ongoing patient care through payment incentives.[46] CMS, through its CED program may support evidence development for certain innovative technologies that are likely to show benefit for the Medicare population, but where the available evidence base does not provide a sufficiently persuasive basis for coverage.[47] A case in point is Transcatheter-Valve Therapy (TVT) Registry, a mutually beneficial effort between CMS, CDRH, and industry.[48] The data generated by MDS can assist CMS in making these types of policy decisions. For example, Medicare coverage decisions are based on the best available evidence; MDS can assist in supplementing the evidence base while allowing access to these new technologies and also give timely access to any safety issue, specifically to the Medicare population, so that CMS may act quickly to determine if a change in policy or other action is needed.

AHRQ is involved in supporting efforts to advance the nation's capacity for health information technology to improve the quality, safety, and efficiency of health care delivery.[49] It has supported electronic data infrastructure projects that connect research with health care delivery and provided a roadmap to build learning health systems.[126] AHRQ has also supported the continued advancement of patient registry frameworks to support evaluation of the safety and effectiveness of medical devices as well as drugs.[50] Moreover, these projects demonstrated the feasibility of collecting patient-reported information during routine clinical care and using it for research, safety surveillance, quality improvement, and clinical care. In 2012, AHRQ in collaboration with the National Library of Medicine designed and deployed the Registry of Patient Registries (ROPR) to catalog the inventory of existing registries to improve transparency and reduce redundancy in postmarket evidence generation efforts.[51] AHRQ supports the patient safety organization (PSO) program to improve patient safety and health care quality.[52] PSOs create a secure environment where clinicians and health care organizations can collect, aggregate, and analyze data to identify and reduce hazards associated with patient care. AHRQ (in conjunction with FDA and ONC) revised a device event-specific common format to include patient safety events related to health IT–specific devices for PSOs. MDS has the potential to further the work of PSOs and of ROPR (related to medical device registries) to generate better evidence on the safety and effectiveness of medical devices in patient care in order to improve the safety and quality of health care. For example, CDRH has partnered with industry and the Vascular Quality Initiative (a PSO) to expand indications for devices used to treat dissecting thoracic aortic aneurysms.

ONC's vision is health information accessible when and where it is needed to improve and protect people's health and well-being.[40] This includes leveraging technology to create an environment of continuous learning and improvement. ONC strives to enable electronic sharing of information with health care providers, patients, and caregivers as well as strengthening feedback loops between scientific and health care communities to translate evidence into clinical practice and other settings, and learn how to perform better. Over the last ten years, many health care providers have adopted EHRs and many communities have created successful electronic health information–sharing arrangements. ONC is working to improve adoption of EHRs and to address barriers to nationwide health information exchange to support the promise of information technology to improve health care and health. The MDS is consistent with these goals and can be an important use of EHRs, standardized data, and information

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exchange networks. An MDS that builds on this growing infrastructure can increase the value of adoption and electronic exchange of information and can support consumer engagement using health information technology.

In addition to FDA, other public health agencies,[g] such as state and local health departments, CDC, and Occupational Safety & Health Administration (OSHA), may find value in MDS to support their public health surveillance activities.[h] It may be possible to learn from and coordinate with CDC's national electronic disease surveillance system, which transfers data from the health care system to public health departments.[53] Several states are developing all-payer claims databases that compile data from private and public payers to assess health care utilization and cost.[54]

[g] A "public health authority" is an agency or authority of the United States government, a State, a territory, a political subdivision of a State or territory, or Indian tribe that is responsible for public health matters as part of its official mandate, as well as a person or entity acting under a grant of authority from, or under a contract with, a public health agency. See 45 CFR 164.501.

[h] [A] public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority. See 45 C.F.R. §164.512(b)(1)(i).

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CHAPTER 2

The Long-Term Vision of a National Medical Device Postmarket Surveillance System

This chapter outlines the Planning Board's recommendations on the mission, principles, and key functions for a National Medical Device Postmarket Surveillance System (MDS) designed to meet the challenges of developing, regulating, and using innovative medical devices in the 21st century.

I. System Mission

Proposed mission:

The National Medical Device Postmarket Surveillance System (MDS) supports 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.

The Planning Board envisions MDS supporting the generation of timely and reliable information on medical device benefits and risks by coordinating a national data infrastructure that uses data captured as a part of routine patient care. Information generated through MDS should meet priority public health and health care needs related to medical device safety and effectiveness, including:

- Providing better information to support patient, clinician, health system, and payer decisions (including earlier reimbursement) about medical devices,
- Informing CDRH's regulatory decision-making to ensure safety and accelerate product innovation (facilitate premarket approval/clearance and expansion of indications for existing devices),
- Mitigating potential harms by supporting rapid response to device safety problems,
- Gathering information about existing products to inform the development of new and innovative devices, and
- Improving health outcomes through better decision-making based on information from real-world experiences with medical devices.

The Planning Board recommends MDS be implemented and managed by a multi-stakeholder public-private entity with sufficient authority and funding to effectively support meaningful medical device surveillance. MDS should be an integral component of the national health information infrastructure working toward a learning health care system and support a harmonized national approach to medical device evidence development.

This chapter will focus on the long-term vision of the overarching principles and priorities for MDS. Chapter 3 will provide details on the leadership, organization, and sustainability of a public-private partnership proposed to implement MDS. Finally, Chapter 4 will include the Planning Board's recommendations for potential next steps on the path toward the long-term vision of MDS.

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II. Overarching System Principles

To accomplish its mission, MDS should be developed and implemented with the following set of core principles.

Guided by FDA Device Surveillance Priorities
While we envision that MDS will reflect collaboration among a range of stakeholders, data sources, analytic methods, and users, it is critical to keep in mind that the system will initially be implemented to address critical questions on the benefits and risks of devices that cannot be adequately addressed using existing tools. For this reason, FDA will play a critical role in identifying the specific questions that should be addressed through MDS.

Patient- and Clinician-Focused
Patient needs and perspectives should be a central component of surveillance activities. MDS should support the capacity to generate information that addresses surveillance questions of high interest to patients and the clinicians that care for them. The system should promote mechanisms for patients to contribute information (e.g., performance, safety, and quality of devices they receive, care experience). MDS should also support timely and transparent dissemination of meaningful information to patients and clinicians to help inform decisions about their care. As providers of patient care, clinicians need a system with which they can obtain up-to-date information about the medical devices they use and to which they can provide medical device data based on patient care. To help assure these capabilities are achieved, patients and clinicians should be well represented in the leadership and management of the system.

Integrated Component of a Broader National Effort
Consistent with the objectives of the learning health care system, MDS should be developed as an integrated component of a broader national health evidence development infrastructure. The Planning Board believes that any effort to create a standalone, isolated system will significantly increase the work required to develop data and conduct analyses on surveillance, lowering the value of the system and threatening its viability. The system should partner and collaborate with other health evidence development efforts to ensure that the various systems are aligned and complementary. Close connections to other health evidence development groups should promote the cross-pollination of expertise, methods, and technological advancements. The system should also leverage existing and developing health information technology standards and health information exchange infrastructure that is supported by the work of ONC to minimize duplication, cost, and time to capture and make data available for the system. The Planning Board should collaborate with health information exchange governance entities to enable use of existing systems and frameworks for MDS.

Multi-Stakeholder Collaboration
MDS is expected to use data generated by many different stakeholder groups—patients, consumers, clinicians, providers, payers, the device industry, public health agencies, and researchers—for a variety of different functions. These same stakeholders will also make use of the information generated by the system. All stakeholders should be engaged in the leadership of the system. In many cases, uses of much of the data by MDS will be secondary to the primary purpose of the source data (e.g., administrative claims, EHRs). In developing policies for using these data, the system leadership should be representative of the diverse stakeholder groups, including the data holders who have knowledge and expertise regarding the source data and can also provide input on the type of information and value that

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can be derived by the system, and seek to balance their needs and viewpoints with those of patients and the public.

Fulfilling a clear and focused mission given a variety of competitive interests and needs of the stakeholders is an acknowledged challenge, as is engagement and collaboration between different stakeholders. The leadership must be tasked to set the priorities and manage stakeholder expectations and demands to avoid mission creep and maintain the integrity of the system for optimization of patient care and promotion of public health.

Forward-Looking and Continually Evolving
MDS needs to support the ongoing evolution of, and access to, high-quality electronic health information. The system may start with limitations in its capabilities, but should have the capacity to advance with the health care ecosystem to maintain viability and value. It should seek to stay abreast of technological and methodological innovation and to drive programmatic and policy changes through technical expertise and leadership.

Clear Expectations and Transparent Communication
Trust in the policies, methods, tools, leadership, and expertise of the people responsible for collecting, using, and disseminating findings is critical to the success of the system. The system leadership and governance needs to clearly establish the criteria and expectations for participation and uses of the data. This includes parameters about the types and quality of data utilized by the system, clarity about the methods and the development process, how to participate in the system, how data are used and handled, and criteria for publicly disseminating findings. The system leadership must also have mechanisms in place to identify, mitigate, and address real or perceived conflicts of interest. Public support and trust will be founded on the timely and accurate communication of medical device benefits and risks.

Maximizing Utility and Minimizing Burden
MDS should be cognizant of the balance of providing more data and the burden of collection. In order to support the development of more meaningful information, the system should promote stakeholder collaboration to identify mechanisms to seamlessly integrate data collection into the provider-health care systems, claim system workflow, and as an integral aspect of care delivery.

As we have noted, creating a surveillance infrastructure for a single purpose limits its long-term utility and viability. The data within the system has the potential to support a broad range of evidentiary needs for a variety of stakeholders. In addition to using these data to support surveillance in the TPLC process, other important health questions could also be addressed. MDS should work to understand these other use cases and value propositions, coordinate with the responsible external groups to align work where possible, and identify opportunities to streamline reinforcing initiatives.

Respecting and Protecting Data Privacy and Security
Activities involving use of electronic health care data are subject to regulations administered by the HHS, including the “Common Rule” administered by the Office of Human Research Protections (OHRP), and the “Privacy Rule” and “Security Rule” administered by the Office for Civil Rights (OCR) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) The system should actively work to ensure that federal patient-privacy laws, regulations, and ethical standards are maintained within the system.

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While transparency will be the goal of the activities conducted using the national system, some information shared by third parties and collaborators will need to be kept confidential, including, but not limited to, individually identifiable health information, proprietary information disclosed by system collaborators, and data and communications concerning uses and outcomes of the national system that are not yet made public.

III. System Priorities and Functions

MDS should coordinate and facilitate access to a national data infrastructure to support the development of evidence about medical devices. The Planning Board envisions a data infrastructure that coordinates the larger network of data partners who have access to diverse data captured as a part of routine patient care and other routine data collection. These data sources may include, but are not limited to, claims and administrative systems, patient-generated data, EHRs, device-specific and clinical care registries, and the FDA Global UDI Database (GUDID). The data partners may include, but are not limited to, payers, provider organizations, medical societies, manufacturers, public sector agencies, and research organizations. The data infrastructure should be part of the emerging national health information system and leverage new interoperability standards[55] to specifically address medical device surveillance questions. The data infrastructure would then create a platform to enable these data to be efficiently used for evidence development activities for medical devices. Additional guidance on how MDS should coordinate the development, governance, and implementation of the data infrastructure are described in Chapter 3.

Given current needs, the Planning Board recommends that MDS have two distinct sets of functions.

- MDS's ***primary function*** should be to support the timely and reliable development of evidence on the benefits and risks of a device throughout its life cycle for active safety surveillance, and to balance pre- and postmarket data collection.
- MDS's ***secondary function*** should be to leverage its resources to collaborate with external organizations to support other high-priority evidence development needs, such as product tracking and utilization, quality improvement, and economic analyses.

A. Primary System Functions

Active Safety Surveillance

Patients and the public need to be confident that potential safety issues involving medical devices are quickly and accurately identified and appropriately communicated and acted upon. Active safety surveillance uses routinely collected electronic health information to identify potential safety concerns rather than passively waiting for reports of potential adverse events. The current methodological paradigm of active safety surveillance involves large-scale analyses to evaluate potential safety concerns through retrospective, prospective, and near real-time observational data analyses.[56]

MDS should learn from other efforts seeking to develop scalable and sustainable systems to support national-level evidence development activities. For example, the Sentinel Initiative's Mini-Sentinel pilot has developed the capacity to conduct some active safety surveillance of medical products, mainly drugs and biologics.[56] In this process, the Sentinel Initiative has created national partnerships with 18 data partners, which includes nearly 180 million patients,[57] and developed innovative methodological tools to detect, refine, and evaluate potential safety concerns. A second example is the Data Extraction and Longitudinal Trend Analysis (DELTA) network. In a proof-of-concept study, DELTA demonstrated the feasibility of a computerized, automated tool using statistical algorithms to perform prospective,

targeted surveillance for high-risk new medical devices.[58] While these efforts provide some building blocks for MDS, the evolution of new technological tools and methods may change what is possible and may make current approaches outdated. MDS should build on the successes of current approaches but also work to adopt advancements in data infrastructure design and analytic practices.

As noted in chapter 1, some key challenges for active safety surveillance specific to medical devices are technical. In particular, unlike drugs, which can be uniquely identified in current coding systems through the National Drug Codes (NDCs), medical devices cannot always be identified (other than by the manufacturer) at the level of specificity necessary for effective safety surveillance. In recent years, significant progress has been made to change this, such as required labeling that includes UDIs,[59] coupled with steps to encourage UDI incorporation in electronic health information sources[60,61,62] and to pilot studies that use UDIs.[63] Aside from technical issues, policy changes are important as well, such as certification of EHRs to include UDIs. Further steps to accelerate the use of UDIs for device surveillance are discussed in Chapter 4.

The health IT ecosystem is likely to evolve significantly in the near future and may present opportunities that are currently not feasible. In a recent ONC report, a ten-year roadmap was laid out to support the widespread adoption of interoperability standards that may revolutionize how electronic health information is shared.[55]

MDS activities will need to comply with the legal provisions protecting patient privacy. FDA's active safety surveillance activities, conducted under FDA's public health authority, are exempted from the Common Rule and HIPAA Privacy Rule.[64] MDS would be expected to have similar authority for its active safety surveillance activities. However, most FDA postmarket studies are considered research activities under the Common Rule and require IRB approval and patient-informed consent. MDS activities that are considered research must also abide by the Common Rule.

While active safety surveillance systems are still developing, in the future they may be able to ease some current adverse event reporting requirements that often require dedicated data collection and reporting, such as MDR.

Optimizing Pre- and Postmarket Evidence over the Device Life Cycle

Beyond safety surveillance, the MDS can also support other aspects of the FDA's regulatory mission of protecting and promoting the public health. Currently, the regulatory process for device approval or clearance requires many safety and effectiveness questions be more fully addressed before the introduction of new medical devices to market, and limited infrastructure exists to help evaluate additional or modified uses of existing devices that might come about as a result of postmarket experiences.[65] Reflecting the TPLC life cycle (Chapter 1), MDS should be capable of supporting postmarket evidence generation activities that better balance pre- and postmarket data collection, provide benefit/risk assessments, and facilitate device innovation.

The development of the TVT Registry is a recent example of a virtual data infrastructure being used to provide needed postmarket evidence and facilitate premarket approvals and expansion of indications.[66] In addition, the TVT Registry is providing data used for CMS's CED program.[67] By supporting more routine postmarket surveillance capabilities like the TVT Registry, MDS can promote pre- and postmarket evidence development on a broader range of medical devices. Thus, MDS may be used more broadly to monitor off-label uses, embed clinical trials, expand indications of existing devices, and address issues that cannot be fully resolved in the premarket review of next generation devices.

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Effectiveness Research

Similarly, medical devices used in routine patient care may have implications for different types of patients that may not be known or well-defined as a result of premarket studies. In conjunction with safety surveillance, the MDS can potentially support analyses of the effectiveness of medical devices, to further inform risk-benefit evaluations for device regulation as well as to inform clinical decision-making and develop evidence more relevant to particular types of patients. Effectiveness evidence can involve a single product or comparisons of alternative products or interventions (e.g., multiple devices, various clinical approaches). Due to generally smaller effect sizes and selection biases and other confounding inherent in observational study designs, developing reliable evidence on effectiveness is generally more challenging analytically than developing evidence on serious safety problems. For this reason, uses of existing active surveillance systems like the Sentinel Initiative have focused on serious safety outcomes. However, with the collection of additional clinical data to help address biases, and with the use of innovative methods that may also help address bias, the future MDS may be able to provide valuable additional effectiveness evidence to accompany safety evidence.

B. Secondary System Functions

The Planning Board believes MDS can be used to support other high-priority medical device–related activities such as product tracking and utilization, clinician- and facility-focused quality measurement and economic analyses. The data used to support the primary capabilities can also inform inquiries that come from the broader medical device community.

The system should collaborate with external groups interested in 1) accessing data within the system, and 2) coordinating to align evidence development activities. If the intent and design of the activity is aligned with MDS's data governance, the system may work to support these uses by providing access to data, methods development, or offering (but not requiring centralized) analytical support. MDS should coordinate with other programs to promote the adoption of common data standards and requirements, and the use of real-world clinical data (including registries) to minimize data capture burden and improve the quality of information. The guiding principle should be "capture once and use for multiple purposes," especially when EHR data are involved. The governance structure should also outline protocols for appropriate engagement with MDS's resources to ensure they are used for purposes in support of optimal patient care and promotion of the public health rather than for organizational or economic advantages.

External groups may include patient advocacy organizations, consumer representatives, clinicians, hospitals, medical societies, the device industry, public and private payers, registries, independent researchers and research organizations, and government agencies other than FDA.

Potential partners may include the Sentinel Initiative, PCORnet, CMS, NIH, CDC, AHRQ, VA, state-led initiatives, and medical societies. By aligning MDS with these other efforts, the system would be well-positioned to use existing data sources, contribute data from device-specific sources, and prove its value to a broad range of potential participants. A compelling value proposition that appeals to current and future users of medical device data will be essential if the system is to successfully engage data contributors and be sustained by the financial and other contributions that they can provide.

These partnerships should focus on deploying resources in ways that minimize duplication and do not impose new burdens on the health care system. The system should engage with others in coordinated efforts for data infrastructure, methods, and tools to ensure consistency and promote functional

interoperability between related systems to enable data sharing and aggregation, including health information exchange organizations, governance entities that facilitate information exchange, standards organizations, and ONC.

The secondary functions of the system highlight the importance of establishing conditions to access and use of the data, such as protection of individual privacy as well as of proprietary data.[68] Principles for data governance are discussed in further detail in the next chapter.

Tracking and Utilization

Comprehensive tracking and utilization information may be used to promote efficiency and transparency regarding the distribution and use of medical devices. This data could provide a national benchmark for utilization. For example, by providing national estimates of utilization patterns, a better understanding of how frequently and in what patient populations specific devices are used and how actual utilization patterns compare to clinical practice guidelines can be developed. It could also help compare hospital-level utilization to national levels. Manufacturers and health systems may also use the system for tracking medical products to improve supply-chain management and streamline manufacturer-provider and provider-patient communication. Greater manufacturer-patient engagement could facilitate communication about adverse event notifications, recall management, and updated information on product indications, new technical data, and device reliability.

Quality Measurement

As payments shift toward value-based reimbursement models, performance measurement and quality reporting are being refined in electronic data systems used to support payment. Medical devices are an important component of these changes. For example, Medicare physician payments include an adjustment based on reporting on the "meaningful use" of EHRs,[69] an adjustment for reporting on quality-of-care measures or participation in a clinical registry,[70] and a new "value-based modifier" that includes information on quality and cost.[71] In addition, Maintenance of Certification credentialing increasingly involves analysis of data from actual practice.[72] Data needed to capture results of interest for payment and assessment of the performance and quality of providers is likely to overlap substantially with the data required for assessing devices, at least high-priority devices, so that quality reporting requirements could be aligned with those for device surveillance.[73] These steps can help improve data available for surveillance if the efforts are well coordinated. In addition, clinicians may be interested in utilizing the MDS infrastructure as a tool to support quality improvement, especially if it provides them access to more robust clinical information than is currently available and supports longitudinal analyses.

Additionally, accreditation and credentialing organizations, such as NCQA and The Joint Commission (TJC), may be interested in partnering with MDS to meet some of their data and evaluation needs more efficiently than current practices that include medical devices. While the system would be focused on safety and effectiveness of medical devices, it could also contribute important information more broadly to promote public health, for example on the management of such chronic diseases as heart failure and diabetes.

Finally, many efforts such as AHRQ's PSO program[74] are underway to reduce medical errors and other adverse events in the delivery of health care. Because of the significant role of medical devices in many aspects of care delivery and in safety problems, the MDS infrastructure may also be able to partner with these efforts.

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Measuring Economic Value

The growing importance of medical devices in patient care has made the device industry into a multi-billion dollar enterprise.[75] The device industry, investors, policymakers, and payers who work with them may get additional value from MDS if it can help provide a better understanding of the risks and benefits of a device in practice, inform future device iterations, afford understanding of market potential for a new device, or lead to other insights with economic implications.

There are several potential opportunities to measure the economic value derived from the system. It may be possible to measure economic returns of improving upon the efficiency of current practices, such as time gained or resources saved. For example, data from MDS could support health system and payer understanding of device effectiveness and comparative effectiveness to inform value analysis, contracting, and payment for particular devices. Additionally, it may be possible to measure economic value of earlier detection of potential adverse events, such as cost savings from reduced hospitalizations.

IV. Devices Captured within MDS

One Planning Board task was to identify priority device areas for device surveillance. There are tens of thousands of different medical devices on the market today. The range in both complexity of design and associated risks is tremendous. Device complexity and diversity will only increase as technology advances and health care options grow. FDA priorities for device surveillance, and the interests of other stakeholders, will also evolve as new technologies develop and other evidence accumulates. Consequently, setting very specific parameters or priorities about the types of devices that should be captured within the system in the long term is unlikely to be helpful.

However, the Planning Board believes it is essential to prioritize the types of devices captured within the system in the short term. It is not reasonable to expect that all medical devices will be tracked at the outset while the system is being built. It may also not be financially practical from a manufacturer or provider organization standpoint to intensively track all lower-risk devices. A pragmatic approach would be to begin with Class III and implantable devices, the failure of which would be reasonably likely to have serious adverse health consequences. In light of current requirements for implantable device tracking and UDI labeling of Class III (Sep. 2014) and Class II implantable, life-sustaining and life- supporting devices (Sep. 2015), these higher-risk devices may provide an important model for device data with the system.[76] In the future, the scope of the system may go beyond and address concerns of more moderate-risk devices.

Similarly, a related task given to the Medical Device Registry Task Force was the identification of priority medical device types for registries.[77] The Planning Board recognizes that, at least for some devices, registries hold the potential for becoming key data hubs linking EHRs with other key data sources on devices and patients, and may be important elements of MDS. The Medical Device Registry Task Force is well-situated to identify priority device types for registries in the short term. In the longer term, this work should include development of mechanisms to engage stakeholders in the process and criteria for selection, as reflected in the governance processes for the MDS. The Planning Board believes that these criteria and processes can also be used beyond registries and be applied to the broader system.

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CHAPTER 3

MDS Public-Private Partnership Organizational Structure

The Planning Board recommends a public-private partnership (PPP) to develop and manage the National Medical Device Postmarket Surveillance System (MDS). This partnership model was selected because the data models and analytic methods involved will require active and ongoing involvement from CDRH and the private sector. This model has also been used in health care[i] and in other public policy areas to successfully build and maintain significant infrastructure projects that no single stakeholder could accomplish alone.[78,79,80] The partnership should be focused on creating a structure to leverage the interests and strengths of the public and private sectors partners, not only to promote safety and effectiveness, reduce costs and avoid duplication, but also to share expertise, in ways that a public or private model alone could not accomplish.[81]

The public-private partnership approach requires overcoming some distinct challenges, however. While the foundation of the partnership should be designed to serve the public good, public funding is unlikely to be enough to support the entire enterprise. Public funding is likely to be especially important at the beginning, to create momentum and develop the incentives for private sector organizations to contribute resources on an ongoing basis—including data, expertise, and funding—to support the initiative. Therefore, for the partnership to be successful, public and private partners need to commit to long-term goals of the organization and contribute in-kind resources (e.g., data analytics) as well as implement a sustainable model for financial support. In turn, participation in the partnership must offer stakeholders significant value. The long-term success of the system will depend on building strong relationships with the key stakeholders, and ensuring that the work evolves with their needs.[82]

While being a strong multi-stakeholder enterprise could be a significant strength of the future system, it can also create several challenges, since a diverse group of stakeholders will often have competing, and sometimes conflicting, priorities. To advance the work of the organization, the leadership will need to actively work to orchestrate alignment in stakeholder priorities. This process must be carefully managed to maintain focus on critical priorities and sustainability.

I. Organizational Governance Principles

To maintain trust and confidence of all stakeholders in the value of the partnership, a transparent and representative governance structure is required. Given the leadership's role in setting MDS's priorities and policies, the organizational governance policies should address potential conflicts of interest to assure transparent operations, which ensure that the system supports high-quality analyses that are aligned with the mission, and actively promote sustained participation.

Addressing Conflicts of Interest

In building a multi-stakeholder organization, diverse views and priorities will be inevitable, and the organization will need to manage different, and potentially competing, interests. It is essential to have transparent conflict of interest disclosures and processes for the organization and its leadership.

[i] Successful examples in health care include the Reagan-Udall Foundation, the Foundation for NIH (FNIH), the Centers for Disease Control and Prevention Foundation (CDCF), and the Global Alliance for Vaccination (GAVI).

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Creating Public Transparency
The organization should be transparent in how it operates and communicates priorities, methods, and outcomes to the public. The governance policies should set specific conditions for accessing data. The organization should strive to communicate system-generated analyses and reports to the public, while adhering to patient privacy regulations. The organization should develop policies and procedures for public dissemination of findings. For example, results that may have significant public health implications should be made public. The organization should develop criteria and policies to annually report on its performance to the stakeholders and the broader public. These reports should include updates on the organization's operations, finances, governance, and organizational outcomes. The organization should seek to disseminate information developed through the system with the public. It will be imperative for the organization to engage the non-expert community. Particular attention should be paid to ensuring patients and consumers are engaged with the system, and communicating with them to demonstrate its value.

Developing Reliable Data and Methods
The organization will need to develop policies to assure the integrity of the data accessed within the system. The organization should work with national experts to develop policies and criteria to assure the quality and appropriateness of the methods used in data generation, analysis, quality assurance, and dissemination. The organization should regularly evaluate the effectiveness of these policies and processes to maintain high scientific standards.

Defining Value to Ensure Sustainability
The system will only be sustainable if it offers services and products that are valuable (functionally and/or financially) to participating stakeholders. The Board has identified two related dimensions of sustainability. The first refers to the financial viability of the organization that supports the system. The second, and more fundamentally important level, is the sustainability of the system's activities. The public-private partnership model offers an opportunity to bring diverse groups together to support the system.

A. Leadership Structure, Responsibilities, and Selection

The leadership of the system is responsible for setting rules, establishing policies, and managing the organization's activities. The Planning Board recommends that there be three levels of leadership; 1) Governing Board, 2) Executive Committee of the Governing Board, and 3) Executive Director. These governance elements are to guide the activities and conduct of the partnership's efforts to promote effective device surveillance.

Governing Board
The Governing Board will be tasked with defining the organization's strategic direction and priorities for how to best support the MDS mission, establishing key policies, and building the underlying partnerships to develop and sustain the organization. The Governing Board should be responsible for developing and overseeing foundational policies such as the data governance structure, and the expectations for organizational transparency and public communications.

The Governing Board should be comprised of approximately 20–25 individuals representing a broad range of stakeholder groups and expertise. A representative group of this size is large enough to obtain broad input, yet small enough to achieve consensus, set priorities, and oversee program policies. Membership should include patient and consumer advocates, physicians and surgeons, hospitals, health

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plan representatives (including those serving different populations such as Commercial, Medicare, and Medicaid), manufacturers (large and small), government agencies (e.g., FDA, NIH, CMS, AHRQ, ONC), and health IT experts and methodologists.

The membership should be selected through a public nomination and selection process. Candidates should be qualified to participate based upon their content expertise, their ability to represent the perspectives of their stakeholder group, and their commitment to provide the time needed to actively fulfill the Board's responsibilities. Term limits for seats on the Governing Board will have to be established, balancing the need for sustained member engagement with the necessity to broaden participation, to encourage the evolution of the organization and to respond to the changing needs of its stakeholders.

Executive Committee of the Governing Board

An Executive Committee should be drawn from the larger Governing Board membership to oversee the implementation of the leadership's policies, and provide hands-on leadership for the general operations of the organization. This smaller group would be able to more nimbly address organizational needs but would still be closely tied to the larger Governing Board. The Planning Board recommends that the Executive Committee include approximately 5–7 individuals selected by the Governing Board membership. The Planning Board did not want to be overly prescriptive about who should be included in this group but felt that it would be beneficial if it included representation from CDRH, patients, clinicians, regulated industry, and data partners (e.g., health plans or provider organizations), as well as content expertise in business finance and evidence development.

Executive Director

The Executive Director should be appointed by the Governing Board to lead the day-to-day activities of the organization, and to work with the Executive Committee to ensure that the activities reflect the Governing Board's guidance. The Executive Director would be responsible for managing the system operations and for implementing the leadership guidance.

Independent Advisory Councils

The Governing Board should convene independent advisory councils to tackle challenging issues. Specific areas where additional expert input is likely to be needed from leading experts include the following:

- Protection of patients and their privacy: guidance on protocols as well as ethical and legal considerations for properly accessing and using patient health information and proprietary information.
- Scientific and technical considerations: guidance on health IT standards, data models, statistical methods and analytic approaches, and other complex scientific issues that will arise in the course of implementing the surveillance system.
- Finance and sustainability: guidance on methods for assuring the financial integrity of the organization's operations, and the long-term sustainability of the organization.

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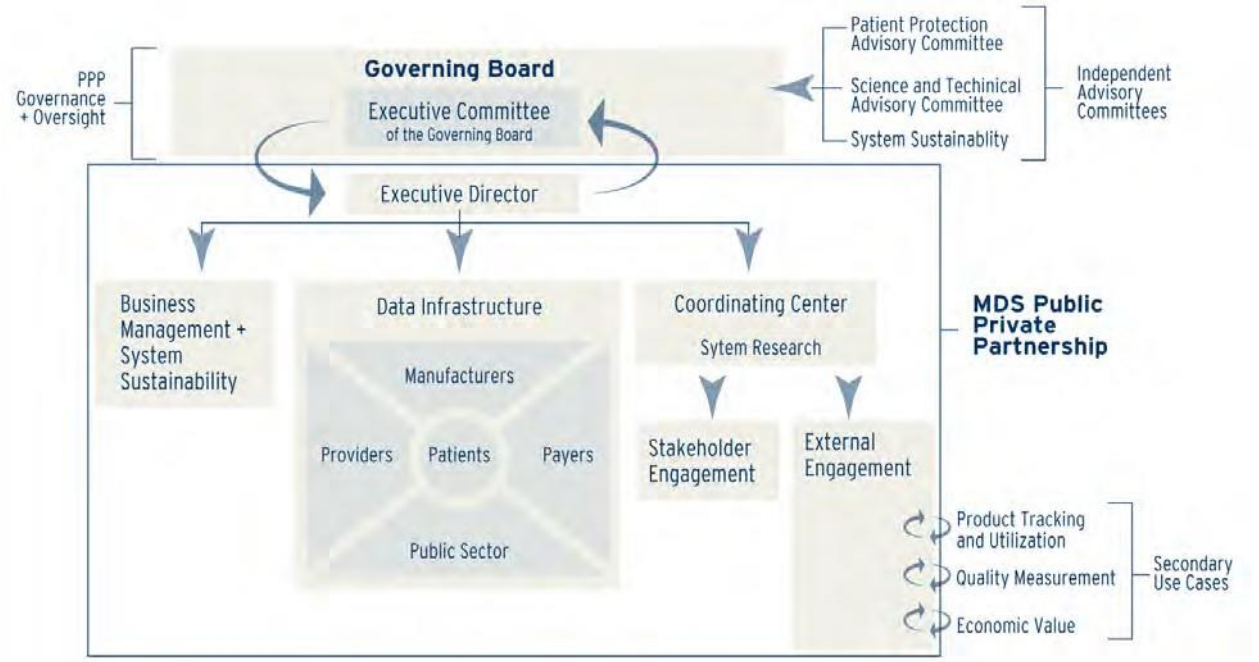
II. MDS Public-Private Partnership Organizational Components

The Executive Director should manage the day-to-day operations with the support of qualified and professional staff. The Planning Board recommends that the PPP's work be organized into the following organizational units—Data Infrastructure, Coordinating Center, and Business Management and System Sustainability (Box 3.1).

Box 3.1: MDS Public-Private Partnership Organizational Structure



A. Data Infrastructure

As mentioned in Chapter 2, the Planning Board envisions the MDS data infrastructure will coordinate the larger network of data partners who have access to diverse data captured as part of routine patient care and other routine data collection. These data sources should include claims and administrative systems, patient-generated data, EHRs, and device-specific and clinical care registries. The data partners should include payers, provider organizations, medical societies, manufacturers, public sector agencies, and research organizations. ONC's emerging national interoperability standards could create the capability to link the data sources, and the data infrastructure would create the platform to enable these data to be efficiently used specifically for evidence development activities for medical devices. MDS would also facilitate access to the data infrastructure for evidence-generating activity sponsors by acting as a central point of access and managing data governance policies and procedures.

The Governing Board of the MDS partnership should be responsible for developing the MDS data governance policies to obtain data and develop evidence from these sources, including encouraging the development of needed data infrastructure and the data models to be used in device surveillance. The partnership should build on existing data infrastructure, models, and methods for integrating data, and track the field in order to take advantage of new models and methods as they are developed over time. The staff of the Data Infrastructure unit of the partnership should be responsible for creating the

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processes and systems needed to implement those policies: 1) operationalizing the data governance policies and data model, 2) coordinating with and supporting data partners to build and manage the data infrastructure, and 3) developing the standards and procedural safeguards to ensure the integrity and security of data accessed through the infrastructure.

Data Governance Criteria

Data governance policies play a significant role in ensuring that partners are willing to participate in the system. The data governance establishes how data is included in, accessed, and managed within the data infrastructure. These policies also need to ensure that the data within the system can be trusted, are accessible when needed, provided in a format that is usable for the intended purpose(s), are of high quality (integrity), and are secure. The following criteria are intended to guide the development of the data governance policies, and the procedures used to implement them.

Protecting Patient Privacy

Many parts of the data infrastructure, particularly the source data systems, will include patient information. The data governance policies should meet the legal and regulatory patient protections. The HIPAA Privacy Rule establishes provisions for the protection of protected health information and appropriate permitted disclosure of information for certain purposes. The Privacy Rule allows covered entities to disclose protected health information to public health authorities[j] for designated public health purposes.[k] The Planning Board anticipates that some MDS activities conducted for FDA will fall under this provision. For example, surveillance analyses of drugs performed for FDA by the Sentinel Initiative are not considered research and fall under this provision.[83] However, other efforts such as postmarket evidence generation activities to support device evaluation for other regulatory decision-making must comply with both the Common Rule and the Privacy Rule.

The Planning Board anticipates that the data infrastructure and other tools developed for the MDS collaboration may also be valuable for other secondary applications beyond device surveillance. However, use of the data for these purposes would need to comply with the regulations protecting patients and their privacy including HIPAA and the Common Rule. For example, under the Common Rule, to the extent that the data involves identifiable private information, evidence development activities would likely require an IRB approval and informed consent or IRB waiver of consent. However, it is possible that some of these activities may qualify for expedited review and waivers.[84]

Given the need to manage the different requirements based upon these two types of uses of the MDS data and infrastructure, the Planning Board believes that two different sets of policies and procedures will likely be needed. The first would be for benefit and risk assessments conducted for FDA (or another public health agency like the CDC) for active safety surveillance and regulatory decision-making. The second would be for any activities conducted for non-FDA sponsors seeking to access the data infrastructure for analytic purposes.

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[j] "…an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate (45 CFR 164.501)."

[k] "A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority (45 CFR 164.512(b1i))."

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Building Data Integrity and Security

For the system to be a valuable source of information, stakeholders must have confidence in the integrity of the data and the security of the data infrastructure. Data governance policies should address the reliability of contributed data, as well as the security of the processes used to transfer, store, and retrieve data in the virtual data infrastructure.

Managing Proprietary Information and Intellectual Property

The system may also have access to proprietary information from stakeholders in the health care industry. For stakeholders to contribute data, they must trust that their data will be appropriately used and protected. To address concerns about inappropriate access and use of stakeholder information, there must be policies for addressing how to manage proprietary information and protect the intellectual property of the contributing stakeholder.

Balancing Transparency and Confidentiality

There should be a clear set of policies about when and how information generated by the system should be made publicly available. Determining what information should and should not be made publicly available, and when, is a difficult task. For example, a safety "signal" often does not translate into a true safety problem. Once a signal is identified as a potential concern, further investigation and validation is needed through more extensive data analysis. As with Sentinel, CDRH may access other data sources to corroborate a safety signal and subsequently take, and communicate, an appropriate course of action. MDS's work should be focused on supporting these analyses. Additionally, once an analysis is completed—whether it be negative, positive, or non-definitive—there must be guidelines in place for communication of the methods and results of the analysis to stakeholders.

Policies and procedures for dissemination of findings will be established by the Governing Board, and should include stakeholder input and public comment. These policies should include guidance about what findings should be made publicly available and when, and how they support the FDA's regulatory responsibilities, and different types of uses of the data. For example, results from safety surveillance or postmarket studies may have significant public health implications, and should generally be made public, including the methodology used to derive those results, whereas results from an independent study may contain proprietary or confidential information that is not of imminent concern to the public's health. The information made available to the public should be meaningful and understandable. Policies should also describe how potential conflicts of interest are addressed and disclosed.

Developing the Data Infrastructure

The Governing Board should collaborate with data partners to develop a feasible and effective data infrastructure and implement policies to ensure the integrity of the data used by MDS. This work should leverage the national standards developed by HHS, including ONC, CMS, and AHRQ, to include a data infrastructure framework and a set of common data elements, building on existing data systems and common data models where possible. The group will also need to develop the mechanisms to aggregate data from multiple sources (e.g., administrative data, supply chain information, EHR data).

The long-term goal is to establish a data infrastructure, potentially with mixed elements, that has enough scope of activity and interoperability across data sources to provide a comprehensive capability for identifying device use and conducting longitudinal analyses of key outcomes and the factors influencing those outcomes. However, this may not be feasible in the early phases of development. Recommendations about potential steps in developing the data infrastructure are included in Chapter 4.

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One of the possible first steps may include identifying key data infrastructure that can be used for initial high-priority pilots.

The system should promote or require UDIs in all data sources and other data standards or data interoperability standards to simplify the process of obtaining key surveillance data. Well-defined standards will help to ensure that the meaning of information captured by different partners is aligned, and is critical to achieve 'semantic' interoperability. Common data interoperability standards also promote the sharing, comparing, and linking of data sets from different sources.

A number of data standards are already in place (e.g., SNOMED, LOINC, RxNORM) or are being developed. However, there remain significant gaps in achieving common use. Several groups are working to develop interoperability standards that could be applied to integrate key data results from multiple sources and terminologies. At this point, however, there is limited information about the effectiveness of their implementation in evidence generation activities.

There is also a need for standardized sets of core data elements, but there are relatively few such sets that have been applied to medical devices at this point. Some groups are developing condition-specific standards for sets of core data elements. For example, the International Spinal Cord Society has developed an International Spinal Cord Injury Core data set to facilitate comparison of studies from different countries. The National Center for Injury Prevention and Control has developed Data Elements for Emergency Department Systems (DEEDS), which are uniform specifications for data entered into emergency department patient records. The National Vaccine Advisory Committee (NVAC) in 2007 approved a new set of core data elements for immunization information systems, which are used as functional standards by groups such as the American Immunization Registry Association (AIRA). The core data elements will naturally reflect the therapeutic areas and outcomes of interest to the developer, and it is unlikely that a commonly used single set will capture all the data necessary for a specific inquiry. That said, having a core set of data elements that can be used in multiple settings and across multiple conditions is highly desirable. Some groups (e.g., International Consortium of Orthopaedic Registries) are already working to harmonize data elements across projects to facilitate future research.

Data Partner Participation

The Planning Board recommends that data partner participation in the system be voluntary. The Planning Board members felt that it would be challenging to enact and enforce mandatory requirements for participation in the MDS system, particularly in the short-term. The Planning Board was also concerned that setting mandates could inadvertently reduce stakeholder support of the system, narrow the types of data contributed, lock in specific data elements and methods that are very much in further development, and for all these reasons reduce the potential long-term scope and impact of activities. While voluntary participation presents its own set of challenges, the members felt that it was the most viable option for the foreseeable future. As noted above, the key challenge in engaging data partners in a voluntary system will be balancing the burden with the value for data partners. Therefore, considerations during final development of the data governance and the data model will need to include how to minimize the burden on contributing data partners, while still obtaining access to needed data for meaningful evidence development activities. Additionally, the system must explore whether voluntary participation will lead to non-representative or non-generalizable results, and whether incentives and other mechanisms can be used to encourage broader participation. For example, the Sentinel Initiative has used payments to data participants, and has made common data models available to help support consistent analyses using Medicare and Medicaid data.

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Fit-to-Purpose Data Infrastructure Development

The Planning Board proposes that the MDS support the development of a tiered data infrastructure. Function should dictate the model. Therefore, the tiers should be designed to meet the data needs of the different types of evidence development activities. The development of the infrastructure should focus on ensuring the protection and privacy of the patients and minimizing the burden of data collection and transfer.

The Planning Board has outlined some of the potential characteristics of the tiers below. These proposed tiers are informed by (but not directly aligned with) the current implementation of the staged data infrastructure development of AJRR.[85]

- **Tier I** includes a small set of core data elements that can be derived from electronic health information, the physician/surgeon, the device, the procedure, and the medical facility. Data captured within this tier should be (relatively) readily available, and accessible for large populations and could support the preliminary safety surveillance activities. The goal is to create a small set of data elements to detect early signs of catastrophic failure (e.g., metal-on-metal hip implants) or adverse events affecting a significantly greater-than-anticipated patient population. These preliminary signals can be used to identify where more in-depth analysis is necessary.

- **Tier II** could link the Tier I data to clinical information captured in EHRs and registries to enrich the data elements to support more sophisticated analyses, including, for instance, risk adjustment for patient body mass index or comorbidities. This more expansive data set can also inform variations in outcomes across populations so that they can be more appropriately compared. While the additional clinical detail may not be critical for basic catastrophic safety surveillance, it would facilitate analyses of benefits and thus support further assessments of the benefits and risks of medical devices in surveillance, and potentially be of sufficient quality to support premarket activities (also Tier III below), and may also be used to support use cases such as quality measurement and comparative effectiveness and safety and economic analyses.

- **Tier III** could continue to build on Tier II by linking to more detailed device and/or clinical care registries for additional information on the patient outcomes and satisfaction, and in-depth evaluations of devices' risk/benefit. Such information may be used to support more sophisticated surveillance studies, including conditions of approval for new high-risk devices or ongoing benefit-risk assessment in higher-risk devices, as well as special evidentiary needs in such areas as comparative effectiveness research.

One benefit of a staged development of the infrastructure based on these tiers can allow data partners to opt in at different levels. Each data partner can base their participation in the system on types of data they own, as well as their individual organizations' needs and priorities. However, allowing data partners to participate at different levels can affect the representativeness of the population. In particular, the sample sizes captured in Tier III may be small and atypical. As noted above, the Governing Board should identify incentives for increased participation to ensure that the data infrastructure includes a robust and representative population.

Beyond the data elements, a principal issue for infrastructure design centers on how the primary data is aggregated, stored, and analyzed. At the extremes are fully centralized or fully distributed models of data maintenance and analysis. Centralized models create a "warehouse" where the data from the data partners are physically stored together, and analyses are conducted by the system that controls the data

warehouse. However, the data owners lose some measure of control of their data once it is entered into the central system. Mixed models use a distributed approach for those analyses or cohort specifications that can be more readily conducted in a distributed manner (e.g., incidence rates, safety surveillance, identification of specific cohorts) but also enable data transfers for combined analysis (e.g., case-control study, cohort study). Distributed or federated models create a meta-database management system that integrates multiple autonomous database systems into a single, "virtual database." "Partner" databases are connected through a computer network. Analyses are conducted on the federated database.[86]

In recent years, there have been significant efforts to explore the feasibility of different data models for large-scale and/or national level evidence development and research collaborations.[I] Data owners have a broad range of restrictions on the use of their data based upon legal, regulatory, and corporate requirements. If the data model established by the system does not address these restrictions, it could create barriers to participation by these key data partners. The Sentinel Initiative and PCORnet use distributed models to address a combination of proprietary, policy, and technical challenges in accessing data (e.g., minimizing identifiable patient information sharing beyond patient care organizations, data ownership and controlling access, assuring that data model and analytic methods used account for data idiosyncrasies known best to data owners). Alternatively, many medical device registries currently use a centralized data model that allows them to more carefully manage clinically detailed data and develop and revise analytic tools tailored to their system.

In the long-term, the Board supports a hybrid approach that exploits the benefits of the various systems within the data infrastructure. The Planning Board believes that the proposed data tiers offer a feasible approach to initiate the development of the data infrastructure and position it to evolve over time. Over the next decade, as the analytical tools, technological resources, and methods advance, many of the current challenges presented may be addressed. In order to ensure the MDS's sustainability, the Board recommends that the Governing Board make it an organizational priority to monitor the development of emerging technologies, data aggregation and analytic methods, and data systems which may evolve into a more durable and reliable model in the future (e.g., big data methods, cloud-based applications).

Facilitating Access to the Data Infrastructure
Access to MDS's data infrastructure and network will be facilitated through the Coordinating Center. The Coordinating Center will oversee the data use agreements, as well as the policies for transparency and dissemination. The Data Infrastructure unit will manage the data governance policies and support the execution of evidence development activities. The role of the Coordinating Center is discussed in more detail in the section below.

B. Coordinating Center

Attempting to build and maintain a single organization with the infrastructure and expertise needed to conduct the aspects of the MDS evidence development activities would be inefficient. Instead, the Planning Board envisions that the MDS partnership will allow coordination with leading evidence development organizations to leverage their capabilities to contribute to device surveillance. The Coordinating Center will be tasked with identifying the organizations with the appropriate expertise and leveraging that expertise through partnerships to access the MDS's data infrastructure to execute the

[I] A few prominent examples include the HMO Research Network, Sentinel Initiative, NIH Collaboratory, Observational Medical Outcomes Partnership, PCORnet and AHRQ EDM systems.

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evidence development activities. Building on existing programs will reduce costs, accelerate implementation, and ease near-term challenges.

The Center should be responsible for: 1) creating and managing data use agreements with partners and/or external organizations utilizing MDS's data infrastructure for evidence development activities, 2) supporting the development and execution of priority pilot programs and, 3) conducting assessments of evidence development activities to identify, adopt, and promote best practices in data capture, analytical methods, and technology changes. To accomplish its tasks, the Center should have three arms—Systems Research, Stakeholder Engagement, and External Engagement.

System Research and Development

A priority of the Center should be awareness of the landscape of organizations and activities relevant to medical device evidence generation. The Center should assess expertise of the broad stakeholder community, identifying organizations that can provide significant contribution to the system. This will allow the Center to understand the needs of the stakeholders, and the strengths and weaknesses of what is currently being done to address those needs. The Center should establish a collaborative structure with this broader community, working closely in areas where there is overlap.

Stakeholder Engagement

While system leadership will include representatives from many stakeholder groups, it is not possible to include the perspectives of all with a stake in medical devices at the leadership level in the MDS partnership. The Stakeholder Engagement unit will be the bi-directional gateway for communication with the broader community and should be tasked with 1) facilitating engagement of stakeholders and addressing barriers, 2) establishing stakeholder forums, and 3) developing transparency criteria to ensure the appropriate dissemination of information. Especially in the early phases of the MDS partnership, the Stakeholder Engagement unit will be closely engaged with the development of stakeholder confidence in and support for its key activities.

The Stakeholder Engagement sub-unit should coordinate regular forums in which system leaders engage stakeholders with information and updates about the system and opportunities to receive broader input. These forums may address a range of issues, such as initial system design features, system policy issues and determinations, the concerns of particular interest groups, and technical issues. The unit is expected to actively work with diverse groups of stakeholders, including hospital organizations, manufacturers, medical societies (e.g., AMA, ANA), manufacturer associations (e.g., AdvaMed, MDMA), payer organizations (e.g., AHIP), and patient/consumer groups (e.g., AARP) to name a few.

The scientific community is a critical stakeholder and knowledge generated by the system should be communicated to this group. Goals for engagement should include fostering development of peer-reviewed literature, technical white papers, presentations to expert audiences, and other activities. Engaging the scientific community has potential in areas of medical device effectiveness, comparative effectiveness, cost effectiveness, and innovation.

External Engagement

The External Engagement sub-unit should function as the entry point for external sponsors that want to access the MDS infrastructure. This unit should 1) facilitate appropriate and secure access to the system by external sponsoring organizations or individuals; and 2) foster coordination with other groups and promote use of standards and tools that are compatible with other efforts. This unit will assess requests to ensure they are consistent with the mission of the system, comply with data governance policies, and

can be fulfilled. It will also have oversight responsibilities to ensure that there are effective requirements in place to comply with privacy and research oversight standards, to maintain the confidentiality of individual health information and stakeholders' proprietary information, and to assure that policies regarding dissemination of methods and results are followed appropriately.

The unit is expected to have ongoing relationships with organizations that are developing electronic health information infrastructure such as PCORnet, CMS, and AHRQ. Coordinating the development and implementation of data requirements among the various efforts will reduce the burden and improve the quality of data collection and analysis. Working with the broader expert community opens up the possibility of more efficient identification of effective, multi-functional approaches to overcome challenges related to privacy regulations, data standards, methods, and analytical tools.

This unit will work with external experts to support the development and piloting of new analytical tools. The ability to actively use electronic health information to generate reliable safety signals is critical for safety surveillance but it is currently not possible given the limitations of existing methodological tools and lack of UDI. While this unit should include experts in this field, it will be necessary to draw from external experts in academia and from other related fields. Methodological work, such as that previously cited on DELTA, has in the past been sponsored by the Medical Device Epidemiology Network (MDEpiNet).

C. MDS Partnership Business Management and System Sustainability

A new national system will require significant financial resources to be sustainable. There will be initial startup costs to stand up the MDS partnership's core functions, potentially in conjunction with conducting some initial pilot surveillance programs—which will also have some startup costs. Once the system is established, core functions (e.g., staffing, operational and maintenance) will require a stable base of financial support. As an example, the Sentinel Initiative has an ongoing budget supported by FDA of approximately $20–30 million per year, which mostly pays for drug safety surveillance analyses using the data infrastructure. The Planning Board notes that this number does not capture all the costs associated with the system for participants (e.g., data partner staffing costs, data systems).

In order to encourage partners to contribute data and expertise to the system, there must be mechanisms to provide financial and in-kind support to encourage participation. These mechanisms should consider payments to data and analysis partners based on the extent of their contribution to the system. Other potential incentives to encourage participation may include greater awareness of key device risk and benefit issues, the ability to take advantage of shared expertise on methods and analytic tools, redistribution of current costs for postmarket surveillance requirements and leading publications related to medical device safety surveillance.

The Planning Board believes that some public funding for core activities and for leveraging private support is necessary. The business model should evolve over time to address emerging needs. While funding could come from multiple sources, the financing strategy must remain consistent with the MDS mission principles and priorities. Given the foundation of the partnership is to create a critical public good, MDS should seek to provide a relatively low-cost, efficient approach to answering key device safety surveillance questions quickly, and to provide a truly "life cycle" approach to facilitate efficient device development and use.

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For private financial support, a range of models is possible, including membership/system contribution fees, transaction fees, and interface/licensing fees. The framework used to determine annual membership fees may be based on the organizational type, size, and revenue, and/or anticipated utilization of system resources. For instance, the fee structure could include tiers that accommodate a range of different types and sizes of organizations, including manufacturers, nonprofits, CROs, academic institutions, and others who support MDS's objectives.

Programs such as Medicare's CED offer potential opportunities to support payers by working to provide a lower-cost alternative to produce better postmarket evidence in these cases. The MDS partnership could focus on working with hospitals, device manufacturers, and other stakeholders to use the system to create a standard mechanism to more effectively develop evidence than would be possible in a "one-off" CED structure. The MDS multi-stakeholder governance process (with its scientific advisory board) should consider how to assure that the evidence questions are being formulated and analyzed appropriately.

In addition, as the MDS system is established, many types of non-CDRH uses of the MDS data and infrastructure will emerge, as we have described in previous chapters. In conjunction with developing the processes and mechanisms for other parties to gain access to the MDS system, the partnership must establish fee structures for these externally sponsored projects. Such projects could be an important source of financial sustainability for the MDS infrastructure.

The system development should aim to assure that opportunities for significant cost savings are built into the MDS planning. As the MDS partnership refines its financing models, it should work to create performance measures for the system (e.g., comparison of current outlays by stakeholders related to postmarket evidence with the expected outlays under the emerging MDS). Some potential opportunities for savings include more generalizable, scalable, and "reusable" approaches to postmarket surveillance registries. For example, it may be possible to use information generated by existing systems like the TVT Registry to build more standardized data models and analytic methods. This type of expansion could enable a broader range of data analyses.

The MDS partnership should also consider developing additional products and services that are aligned with the governance. This may include pre-defined and de-identified data sets (e.g., to describe the population or disease history that may be relevant to the development of a potential future device), training data sets that can be used to validate methods, and training programs on key methods issues. The system may also want to consider developing subscriptions for reports on specific topics (e.g., analysis of utilization trends, clinical practice changes, benchmarking reports, unmet medical needs assessments, market trending).

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CHAPTER 4

Proposed Implementation Approaches and Recommendations

As outlined in the previous chapters, within a decade the Planning Board envisions a National Medical Device Postmarket Surveillance System (MDS) public-private partnership (PPP) that supports timely and reliable surveillance of medical device benefits and risks based on the real-world experience of patients. MDS will be an integral component of the learning health care system by coordinating and facilitating access to the national data infrastructure to support the development of reliable and meaningful evidence about medical devices. MDS should seek to reduce the burden of evidence development for medical devices by supporting more efficient mechanisms to capture and use data collected as an integrated aspect of patient care.

This chapter presents the Planning Board's recommendations for the short- and mid-term steps to achieve the vision for MDS. The Planning Board proposes a two-stage approach to the development of MDS.

- **Years 1–2:** Initiate a short-term incubator project to gather critical information and develop a 5-year plan to develop MDS, including selection of the organizational characteristics of the PPP, governance, leadership, business plan, and data model(s).
- **Years 3–7:** Implement the long-term MDS PPP based on a detailed development plan created by the incubator project.

I. Years 1–2: Create an Incubator Project to Plan the Launch of the National Medical Device Surveillance System

Overview of the Incubator Project

The Planning Board believes that additional steps are critical to designing the operational details and initial launch of a sustainable MDS PPP capable of carrying out the Planning Board's long-term vision. Therefore, the Planning Board recommends initiating a 2-year incubator project tasked to create a detailed development plan for the first five years of the MDS PPP.

The scope and scale of the incubator project reflects the activities needed to complete its goal of developing a 5-year implementation plan for the MDS PPP. The project should quickly and efficiently gather information and undertake pilots to inform the development of MDS. This implementation plan should, at a minimum, include the following:

Recommendations to develop the core system capabilities

- Define the framework for MDS's implementation, including the organizational structure, core tasks, and supporting authorities
- Identify key partner organizations, role(s), and mechanisms for recruitment and collaboration
    - Prioritized opportunities to leverage existing resources
    - Strategies to ensure maximum efficiencies, with a focus on cost and burden
- Propose mechanisms to ensure appropriate patient protections and data privacy requirements
- Identify and prioritize pilot projects to initiate in early implementation of MDS:
    - Broadly applicable approaches to implement the MDS data infrastructure based on the incubator feasibility pilots
    - Key activities that will provide value for individual stakeholder groups

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- Approaches to address critical gaps in evidence

Recommendations for the PPP organizational implementation:

- Potential organization(s) to host the new MDS PPP
- Mechanism for selecting the MDS leadership, including the Governing Board and the Executive Committee of the Governing Board
- Management and operational framework for MDS, including staffing and information technology needs
- Financial projections, including an estimated budget, and potential funding sources such as appropriations, potential members, and service fee structures, and other in-kind contributions
- Transparency and communications strategies

The 5-year development plan should seek to create an efficient and streamlined organization that is aligned with the Planning Board's vision of a public-private entity with sufficient authority, partnerships, and funding to conduct effective and meaningful medical device surveillance. Wherever possible, the plan should use external expertise and resources to accomplish MDS's mission through partnerships that leverage resources and reduce burden. Pilot activities identified and potentially initiated within the incubator project should help create a foundation for establishing these ongoing partnerships.

Fact-Finding Activities, Evaluation, and Prioritization

The incubator project should undertake a series of fact-finding activities to inform the development of the implementation plan. These activities should focus on identifying current and emerging postmarket evidence development activities to identify key partners to build MDS's data network and coordinate efforts across the medical device ecosystem. The incubator project should also work to better understand the diverse needs of the different stakeholders in order to identify potential activities that would add value and expand MDS participation and support.

Coordinate Feasibility Pilot Projects

Targeted pilots could be used to inform more specific plans on how MDS can best be implemented, as well as start building the foundation of the MDS data infrastructure. The incubator project should identify and leverage to the extent possible recent or ongoing projects that test core capabilities and data infrastructures that could ultimately support MDS. For example, there are several projects being launched under MDEpiNet that could directly inform the MDS development plan.[87] The incubator project should also coordinate with MDEpiNet and the Registry Task Force to identify potential priority pilot areas for both the incubator project and to inform the next phase of the MDS implementation (years three to seven).

If there are key technical questions that are not being addressed by existing efforts, the incubator project should conduct a small number of targeted preliminary feasibility pilots to help address them. While it is not practical to fully initiate and complete in-depth pilots within the 24 months of the incubator project, it is possible to test the feasibility of some potential pilot approaches and use this experience to help define initial steps for the implementation of MDS (i.e., years three to seven). Any pilots conducted under the incubator project should have discrete tasks, seek to build upon successful existing efforts, and leverage the expertise and resources of different stakeholders. The pilots should also seek to support and advance ONC's interoperability framework.[55] The Planning Board has proposed three potential pilot concepts to assess possible solutions for key challenges in device surveillance (See Appendix A).

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Develop and Execute the Criteria and Process for Selection of the MDS Leadership and Host Organization

The Planning Board recommends the incubator project define the initial selection criteria and process for determining MDS's leadership and the host organization. The Planning Board believes that MDS leadership should have multi-stakeholder representation and that members be selected using a public process as noted in Chapter 3. The model is one of collaboration and the premise is that the effort will be stronger with broad participation. Qualifications for leadership members should also be based upon their subject matter expertise, ability to represent the perspectives of their stakeholder group, commitment to the MDS mission, and ability to provide the time and effort required to engage in the Governing Board's activities. Additional consideration will need to be given to the selection of the Executive Committee of the Governing Board which is intended to be a small (e.g., five to seven members) "hands-on" group charged with overseeing the execution of the Governing Board's policies by the Executive Director.

The Planning Board believes that a larger existing organization could potentially host MDS's public-private partnership. As noted in Chapter 1, there are number of current organizations engaged in supporting the development of a learning health care system and medical device evidence development. Potential host organizations must be capable of providing organizational support to the emerging PPP. The criteria for selecting the host should consider the organizational attributes that would best support a large infrastructure development effort including core business capabilities (e.g., contracts management, financial stability), related content expertise, existing partnerships, non- or for- profit status, academic affiliations, and alignment with MDS's mission to avoid potential conflicts of interest. If no existing organization is identified that can meet these criteria, the incubator project then will need to evaluate the feasibility of creating an independent entity to support MDS.

Incubator Project Leadership, Funding, and Accountability[m]

Based on the scope of work outlined above, the Planning Board recommends that FDA collaborate with other public and private stakeholders to provide approximately $5–6 million in funding for the two-year incubator project. These funds should be used to support the project staff and a small number of short-term pilot feasibility studies.

There are a variety of organizations capable of conducting the incubator project. Therefore, the Planning Board recommends that FDA select the organization responsible for conducting the incubator project through a public process including request for proposals. The Planning Board recommends that FDA consider the following attributes when selecting the organization to manage the incubator project: 1) core organizational expertise relevant to the tasks; 2) existing set of activities aligned with the incubator project's goals; 3) demonstrated ability to create strong partnerships with other key stakeholders and contributors; and 4) the capacity to quickly initiate the project. The Board recommends that the work of the incubator project be conducted by a core staff with experience in project management, regulatory policy, program design, technical methods (e.g., IT, informatics, epidemiology, and biostatistics).

The incubator project should be overseen by a group of representatives drawn from key experts and stakeholders, including patients. The Planning Board noted that in order to get this project initiated quickly, the leadership would need to be engaged and able to quickly get up to speed with the incubator project's tasks. If needed, Planning Board members are committed to continuing to support the

[m] Planning Board members representing federal agencies abstained from the Board's deliberations on the report recommendations on potential funding levels and sources.

incubator effort. At the end of the 24-month project, the final development plan should be submitted to FDA.

II. Years 3-7: Establish the National Medical Device Postmarket Surveillance System Public-Private Partnership

The second phase of work will focus on implementation of the 5-year MDS plan produced by the incubator project. The first step taken should be the selection of the MDS's founding Governing Board and the members of its Executive Committee. Once leadership is in place, the Governing Board can select an organization to house the PPP, and engage an Executive Director and the core staff for MDS.

Guided by the five-year development plan, the Governing Board should set and oversee the strategic development priorities, start to build and sustain broader stakeholder participation, oversee implementation of the organizational plan, and establish how it will measure its progress on goals. The Executive Committee and the Executive Director should establish partnerships with other evidence development organizations and data partners.

The Planning Board has identified the following priority policy and program issues for the Governing Board to address:

- Ensuring that MDS is integrated into the larger national infrastructure for evidence development
- Forming key strategic partnerships with other medical product evidence development activities (e.g., Sentinel, PCORnet, best practice device registries)
- Developing the data infrastructure policies to ensure that patients' privacy is protected

Integrate MDS with other National Evidence Development Activities

The Planning Board believes it is a priority to ensure that MDS is aligned with, and is an integral component of, the broader national health evidence development infrastructure. To achieve a comprehensive surveillance system for medical products, MDS should actively coordinate its efforts with others to take advantage of synergies and minimize duplication of effort whenever possible. Where possible, MDS should also work to leverage existing data collection and analysis efforts, including:

- Identification of best practices in data collection, integration, analysis, and dissemination
- Identification of best practices in IT infrastructure
- Validation of data models and analytic methods using observational data
- Development and validation of additional data elements (e.g., PROs, patient-generated outcomes)
- Establishing a library of resources and expert networks that can support research among stakeholders and across use cases

While MDS is focused on medical devices, the Governing Board should develop strategies to coordinate its efforts with evidence development activities that are not specific to medical devices. In particular, MDS should partner with FDA's Sentinel Initiative to support its expansion to include medical devices as mandated in the 2012 Safety and Innovation Act (FDASIA).[88] Currently, a number of efforts are underway to develop large-scale or national systems capable of generating evidence on patient care and outcomes. For example, federal agencies including NIH,[89] ONC,[55] CMS,[37] CDC,[90] and AHRQ[39] are all engaged in efforts to facilitate the development of systems for generating evidence. Many states and regions are also working to develop health information exchange systems[55] and APCDs.[54]

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Partner with Key Organizations

The Governing Board should establish partnerships with organizations that can support its efforts with core expertise and tools. The Governing Board will have information available from the incubator project's environment scan and pilot activities to begin to work with key partner organizations.

FDA's Sentinel Initiative, MDEpiNet, and PCORnet are examples of groups that can contribute significantly to the development of a national system. The Sentinel Initiative has well-developed relationships with a growing set of data partners with strong interests in surveillance and evidence development. Sentinel should be able to integrate with many MDS functions as UDI and clinical information for device surveillance becomes available. The Reagan-Udall Foundation's IMEDS program could provide valuable experience in governance, methods development, and stakeholder engagement to support surveillance activities. Based upon their current mission to develop data sets and analytic methods related to medical devices, MDEpiNet is well-suited to support the methodological needs of MDS. PCORnet's emerging capability and capacity to leverage electronic health record systems for comparative effectiveness studies may also be a valuable resource and create opportunities for pilot activities. This will be particularly important as PCORI is working to identify ways to ensure the network is sustainable through other sources of support. MDIC's work in patient-centered benefit-risk assessment development is also a potentially valuable source of data, methods and evidence. MDISS is also about to launch a partnership with the National Critical Infrastructure Information Sharing & Analysis Centers to develop and maintain a postmarket system for monitoring cyber-vulnerabilities of medical devices.[91] Strong partnerships with these and other organizations will harness the expertise of external stakeholders and be critical to MDS's development and sustainability.

Protect Patients and their Privacy

Protecting patients and their privacy is critical to MDS's mission and should be a priority for the incubator project. As noted in the previous chapters, there are different regulations governing public health surveillance activities versus other types of evidence development activities and research.[92,93,94] These regulatory structures should be a central consideration for MDS as it builds a system to support multi-use, large-scale, multi-stakeholder, and collaborative evidence development activities. Given the importance of FDA's mission to protect the public health, the incubator should focus on policies to support FDA safety surveillance activities in the initial implementation of the system. There are a number of current approaches that MDS could adopt to ensure privacy protections for patient data for FDA-sponsored safety activities.

In order for MDS to perform evidence development for non-FDA activities, even if they are safety-focused, the system will need to explore other mechanisms to ensure the protection of patients and their privacy. This issue is not unique to MDS and other groups are also working to find solutions to protect patient data and meet research requirements for expanded, non-FDA uses of the types of real-world data. For example, the IMEDS program has been working to develop policies for non-FDA access to the Sentinel Initiative's data and research infrastructure.[95] PCORnet is working to develop IRB processes to enable local sites to participate effectively in national activities while providing better information and appropriate protections for patients.[42] NIH is also working to draft policies on IRB process for multi-site research.[96]

Many patients already consent to have their information used for evidence development at the time of care (e.g., prior to surgery). Without access to the patient's consent information, organizations holding the patient's electronic health information are not able to use or share data for external evidence development purposes beyond safety surveillance. Due to this limitation, the Planning Board believes

identifying reliable mechanisms to efficiently capture and share patients' permission (e.g., informed consent) to use PHI data for broader medical device postmarket evidence development activities will be an important issue for MDS in the initial phases of its implementation.

The incubator project should begin to identify the current challenges of using data for non-FDA activities and partners as part of its work to inform the five-year implementation plan. In years three to seven, the Governing Board should collaborate with other groups like IMEDS and PCORnet to ensure a consistent approach across different efforts to protects patients and their privacy, and also support large-scale evidence development more broadly.

Years 3–7: Public and Private Financial Support for Phase Two of the MDS Implementation[n]

The Planning Board has recommended that the incubator project include the development of a proposed budget with recommended sources of funding. While the long-term vision for MDS is that it be a multi-stakeholder effort, it will need seed funding to get started. Given that a core function of MDS is to support FDA's device surveillance responsibilities, some initial support from FDA to develop the system is essential and appropriate. Similar limited, core support from public sources has been essential for the successful launch of other initiatives such as the Sentinel Initiative[97,98] and the Reagan-Udall Foundation's IMEDS program.[99] Without this initial support and active FDA engagement, it will be difficult to assure the purpose and sustain the momentum necessary for other stakeholders to fully engage in the development of MDS. The Planning Board believes that leveraging such core public funding from FDA and other public sector agencies is the most effective way to build a medical device focused, multi-stakeholder, public-private partnership with broad participation.

The Planning Board recognizes that it is a challenging time for public funding for a national initiative on device surveillance, and that FDA does not currently have specific appropriations dedicated to support such an effort. While Congress enacted legislation in 2012 mandating FDA to expand the Sentinel system to include medical devices,[88] it has not directed appropriations, user fees, or other resources to fund this work. The Planning Board believes that more explicit Congressional support is needed to create and sustain the needed infrastructure for a robust system of medical device surveillance in the U.S. In the past year, Congress has started to actively discuss additional legislative actions to support more efficient innovation including better postmarket evidence on FDA-regulated products. Given the importance of reliable postmarket evidence to support the public health and FDA's mission, the Planning Board believes that these deliberations should include support for the development of the MDS system.

As noted in the previous chapters, the Planning Board believes that the costs and time to develop MDS could be reduced by efficiently building upon existing programs and tools—especially in the near term. Potential building blocks include existing clinical registries, longitudinal electronic data systems built on patients' clinical and claims data, developing efforts based on UDI capture in EHRs, and other systems used by health care organizations to improve value derived from care, both in terms of patient outcomes and cost. Other potential partners include emerging multi-stakeholder collaborations designed to facilitate progress toward a learning health care system. One such partner is PCORI, which is using public funds to support public-private collaborations on developing comparative effectiveness evidence. The Planning Board also notes that not all of the resources need to be provided by FDA. It is

[n] Planning Board members representing federal agencies abstained from the Board's deliberations on the report recommendations on potential funding levels and sources.

also possible to leverage other public sector evidence development activities, including current efforts for safety surveillance for drugs, public health surveillance, and clinical care quality and effectiveness.

For a national initiative of this scope, there are considerable challenges to address for which the private sector will be needed to participate and provide funding. There are numerous public-private partnerships supporting the drug industry's work to develop better evidence. As a result of the differences in the medical device and drug industries' business models, there are currently few partnerships supporting evidence development for medical devices. The medical device industry has voiced support for a more reliable postmarket surveillance system, but companies and health care providers are also concerned that the burdens associated with any new system would only be added to existing regulatory requirements. In order to garner meaningful support from the private sector, MDS would need to demonstrate that it could more reliably support safety surveillance activities and potentially replace less effective and costly programs such as MDR and resource-intensive registry reporting.

Until more detailed information is generated by the incubator project, the Planning Board believes that at this time it is not possible to specify with certainty the public and private funding needed to support MDS in years three to seven. However, based on other activities with similar missions and scope,[100,101] the Planning Board roughly estimates that the cost to implement and maintain the system over the first five years will be approximately $200–250 million in federal and private sector funding.

As point of comparison, the Sentinel Initiative launched the 5-year Mini-Sentinel pilot program in 2009 with approximately $120 million.[97] This funding supported the development of Sentinel's core staffing and the data infrastructure, as well as the execution of FDA surveillance activities. The Mini-Sentinel program developed a distributed system using a common data model for claims data. The program includes 18 data partners and many of them already had experience using their data for safety surveillance of drugs. AHRQ provided approximately $100 million over 3 years to develop the initial infrastructure to collect and use electronic health data for comparative effectiveness research, and some quality indicators and clinical care.[102] MDS should seek to partner with existing systems like Sentinel and PCORnet to leverage their data networks and capabilities. However, these systems are currently not designed for medical device surveillance and additional resources would be needed to enable them to capture device-relevant data. In order to conduct medical device surveillance, MDS will need to map and efficiently link new data sources and will likely need to include more data partners. Many of these new data partners have not yet begun to use their data for this type of evidence development and the costs to support their participation in the system will likely be higher.

While this is a significant funding requirement, the Planning Board does not envision MDS as a large organization that seeks to perform all of its activities in-house. Rather the Planning Board's vision of MDS is as an agile organization focused on coordinating and facilitating the work of external partners and related initiatives to accomplish its objectives. The Planning Board anticipates that approximately a third of the funding would be used to develop and support the MDS organization and the data infrastructure, and contracts with partners implementing priority pilot projects addressing critical evidence development challenges. A much larger portion of the funding would likely be used to support evidence development activities performed through the collaborative network, such as high-priority FDA-funded safety surveillance analyses, and industry-funded safety and effectiveness studies (e.g., mandated postmarket studies, indication expansion studies).

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Technical, Methodological, and Programmatic Challenges in Medical Device Surveillance This section highlights the Planning Board's conclusions on priority technical and methodological issues facing the development of MDS. The Planning Board has included recommendations about potential pilots (see Appendix A) to be initiated during the incubator phase (years one to two) to assess the feasibility of certain approaches to inform the implementation plan. The incubator project has also been tasked with identifying and prioritizing how MDS will address key challenges in phase two (years three to seven).

Table 4.1: Current Challenges to Medical Device Surveillance and Potential Pathways to Address Them

Goal	Current Challenges	Potential Pilots	Building Blocks
Adoption of UDI in health IT infrastructure	• Investment cost of automated capture technology • Investment cost in adapting current data sources • Data transfer and system interoperability • Establishing UDI adoption as a priority initiative	• Evaluate the effectiveness of UDIs in identifying devices within the health care system • Leverage hospital systems and early adopters of UDI in provider settings	• Major health care systems' UDI integration • Bipartisan Congressional support for including UDI into claims forms • Certification of EHR technology for UDI and meaningful use objectives
Sophisticated safety surveillance and evidence development for select, high priority devices	• Data entry burden • Developing methods and analytical tools • Data security	• Utilize registries created for clinical research and/or CED to conduct active safety surveillance on targeted medical devices	• DELTA system capabilities (NCDR application) • Other major registry surveillance methods (TVT, INTERMACS, AJRR/ICOR)
Basic population-level safety surveillance, utilization monitoring, and evidence development for broader range of devices	• Lack of important clinical information in claims (e.g., UDI, revision rates) • Developing methods and analytic tools • Data source fragmentation (like EHRs)	• Leverage existing population-based surveillance systems like Sentinel to conduct device-specific safety surveillance and evidence development	• Device-specific registries • Mini-Sentinel and collaborating institutions • IMEDS • MDEpiNet PPP
Patient-reported evidence on device performance and safety issues	• Lack of easily accessible and user-friendly means for patients to contribute patient-reported outcomes • Lack of validated methods and analytical tools	• Leverage patient networks	• MDIC • PCORnet and PPRNs • Patients Like Me • Disease-based registries (e.g., CF Foundation, MyMeds and Me[103]) • NIH PROMIS

The most important technical challenges the Planning Board foresees in this domain include: implementing UDIs, supporting health IT interoperability, minimizing burden of data capture, and engaging patients. These issues may be addressed through pilots, program design, or potentially working to change current policies. Any activities undertaken by MDS should attempt to leverage existing building blocks, and should be focused on scalable and generalizable approaches that build the long-term capabilities of the system. Some potential pilot areas are summarized in Table 4.1.

A. Data Infrastructure Challenges

Adoption of Unique Device Identifiers

The implementation and adoption of UDIs is a critical component to unlocking medical device information. As outlined in Brookings' UDI roadmap, "Unique Device Identifiers (UDIs): A Roadmap for Effective Implementation,"[67] there are a number of data sources from which UDIs could be collected to facilitate surveillance and evidence development for medical devices, including claims, EHRs, and registries.

A multi-pronged approach to ensure widespread adoption and use of UDIs in electronic health care data by integrating UDIs into EHRs, medical device registries, and administrative claims systems is supported by the majority of Planning Board members.

An area of contention is the integration of UDIs into claims data. Several groups, including some members of Congress,[62] have endorsed the incorporation of UDIs into claims systems citing the potential benefits to the public.[67,104,105] Some payers and hospital systems are opposed to this change citing the costs associated with modifying the claims transaction forms, reforming the transaction process, and limitations of the data-handling capabilities. Given the high costs, these groups assert that it is hard to justify this change without being able to quantify the real value the new data will bring and how this approach compares to direct data capture from EHRs and registries. As a result, some Planning Board members oppose the inclusion of UDIs in claims data as a component of the adoption strategy. The National Committee on Vital and Health Statistics has recommended voluntary pilots (between providers and payers) to assess value and cost of UDI in claims.[106]

EHRs are a growing source of digital clinical data that have the potential for being rich sources of information on medical device safety and effectiveness. There is increasing support by some EHR vendors for incorporating fields to capture UDI, as well as support by ONC and other stakeholders to create EHR certification criteria and to include UDI capture as part of Stage 3 of the Medicare and Medicaid EHR Incentives Program requirements.[107] Additionally, there is work at some U.S. hospital systems to scan and store UDIs of implantable devices in their HIT systems, creating the link between device and patient.

In the long-term, MDS should promote and work to support other efforts to incorporate UDIs into the EHRs so the relevant information is captured where it can be used to support patient care. Incorporating UDIs into the patient record could allow linkage to FDA's Global Unique Device Identification Database (GUDID) and other data sources.[o] This could facilitate populating the patient record with clinically important device attributes, more comprehensive information about the devices to inform patient care (e.g., MRI compatibility). This could also allow EHRs to generate a "medical device list" (as conceived under Meaningful Use) similar to medication lists, available for use by clinicians as needed for revisions,

[o] FDA's GUDID will be available for use by mid-2015.

emergency surgeries, recalls, or other purposes and that could be shared with patients. Capture of UDI in EHRs is a critical step for comprehensive availability of medical device data for clinical care and for postmarket surveillance purposes.

Some commercial EHR and procedural software vendors have begun work on incorporating fields that hold UDIs into their products. Progress has been slow due to lack of widespread customer demand to date, and vendors are concerned that these types of system modifications will lead to a lack in uniformity and expensive implementations. The Planning Board recommends that MDS coordinate with ONC and EHR vendors to develop a core set of requirements to mitigate the burden of implementation and to help ensure the national system's needs are met.

Clinical registries are currently one of the few sources that contain details in one location about patients and devices used in procedures. Incorporation of UDIs into existing registries is an important initiative supported by Planning Board members. Necessitated is capture of UDI at health care delivery sites and data transfer to registries as well as creation by the registry of fields that store UDI and associated attributes.

UDIs are intended to appropriately identify devices for purposes of tracking them through the health care system. Some aspects of the UDI Rule may need to be refined as practical experience from manufacturers and GUDID becomes available. For example, there are currently no rules governing the types of changes to devices that necessitate changing UDIs, and not all parameters that may be changed are represented by the 62 elements required by FDA in the GUDID database. As a result, there is the potential for variability in how companies are assigning UDIs. Another potential issue is the multiple standards for the identifiers.[61] While some groups have advocated for the adoption of one standard, others are working to develop an exchange format that should eliminate such concerns.[108,109]

Supporting Health IT Interoperability

Health care delivery sites will need a higher level of information technology capabilities to both capture UDIs at the point of care and then be able to transfer these data to be used for evidence development activities. In January 2015, ONC issued a roadmap to advance interoperability in the health IT infrastructure in ten years.[55] MDS's leadership must work to advance the emerging national health information infrastructure to link diverse data sources and types, particularly EHRs across varied health care environments.

Minimizing Burden and Errors of Data Capture

Burden of capturing data for postmarket evidence development is a serious concern that must be addressed for MDS to succeed. For example, the TVT Registry requires providers to submit more than 300 data elements, which has been estimated to take a trained professional 49 minutes per data entry form. Between the cost of the registry fees and additional staff time to support the registry requirements, the financial burden for individual clinical site can be extensive.[110] In addition, providers are increasingly asked to report quality measures to payers as a condition of reimbursement, which requires staff to put in additional administrative hours to complete.[111] It is critical that the data entry requirements be minimized to the greatest extent possible if it is to be sustainable and supported by physicians and hospitals whose buy-in is critical to this national effort.

The goal should be to capture data accurately and efficiently once, and use it for multiple purposes. MDS should support efforts to coordinate and integrate reporting requirements into provider workflow,

support efforts to automate capture of data elements (e.g., UDI), and leverage data submitted to meet existing reporting requirements such as PQRS[70] and QCDRs.[112]

Minimizing errors in device data capture is critical. Manual entry of device identifying information is burdensome and prone to error. Automated capture of UDI is still a developing area. MDS, through pilots and subsequent work, must partner with stakeholders to explore and support mechanisms (e.g., test electronic capture systems such as barcode scanning, and systematic use of codes in EHRs) that reliably and automatically capture UDIs at the point of care.

Engaging Patients

The Planning Board believes that MDS should be centered on patients and their needs. The system principles stipulate that patients should have a role in MDS's leadership, ongoing input into its activities, and access to meaningful information about medical devices. It is also essential for the system to support mechanisms for patients to contribute information about the safety and performance of medical devices. The Planning Board believes that it is possible to create a variety of easy-to-access and easy-to-use tools so patients are able to submit data. These tools could be accessed online, in physicians' offices, integrated into payers' systems, or supported by product registries. The transparency of device safety and performance is critical if patients are to become more informed decision-makers about their health and treatment options. It is currently a challenge for physicians and the medical device industry to fully educate patient on their devices and how to identify potential safety concerns. MDS should identify simple, accessible, and effective means to disseminate information derived from the data infrastructure to patients and their clinicians.

The Planning Board recommends the MDS leadership coordinate its activities with current efforts seeking to build validated tools that capture the patient experience and share information with patients. For example, the medical device industry and the public sector are working to build standards for the development, validation, and utilization of patient-reported information. The MDIC Patient-Centered Benefit-Risk (PCBR) Project[113] and NIH's Patient Reported Outcomes Measurement Information System (PROMIS)[114] are aiming to leverage patient-generated data to inform clinical and regulatory decisions on existing and new medical products. PCORnet is developing a national-scale clinical research network to study treatments and develop better evidence on outcomes and patient preferences.[42] Patient advocacy organizations such as PatientsLikeMe[115] are working to empower patients to share their experiences with illness and treatment to help themselves and others in making better, more personalized decisions about their care.

B. Methodological Challenges

Obtaining data needed for MDS is not sufficient for developing valuable evidence. There will need to be ongoing advancement in the methodological tools to support reliable, rapidly executable data integration. MDS will need to work with content experts to support the development and refinement of rigorous and appropriate analytic techniques for evaluating hypotheses about device safety and effectiveness using real-world data, including methods that address channeling bias where higher-risk patients are more likely to receive or use new devices.

Adopting and Adapting Existing Common Data Models to Support the Data Infrastructure

The use of individual patient data from multiple sources has clinical and methodological advantages. More data may increase the power to determine effects more precisely, representatively, and across more specific subpopulations. Richer data also permit more sophisticated analyses to address potential

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confounders and potential biases. More diverse and rich data sources and types also create some significant challenges both in data integration and analytic methods. MDS should work to support the development of more robust methods for efficient data integration, taking into account factors such as varied coding systems and units of measurement. On the other hand, more complex data from heterogeneous sources means there is greater potential for missing data and the introduction of additional systematic bias into evaluation studies through selective availability of information. Further, as the sophistication of health IT tools increases, so will the ways in which those tools are used in clinical practice. As a result, the data derived from those systems will also evolve, necessitating continued investments into the most methodologically rigorous uses of data for evidence development.

Several data models exist for capturing important clinical information consistently from claims, EHRs, and registries. Rather than developing a new data model, the Planning Board recommends the adoption, adaptation, and expansion of current data models. Potential data models include those developed by Sentinel, OMOP (now being further evaluated in IMEDS), PCORnet, CMS, and device registries. Given the current diversity of therapeutic areas, device types, and study design of individual device registries, widespread adoption of a comprehensive common data model will be problematic in the near- or mid-term. The model(s) adopted by MDS should reflect the unique needs of the proposed tiered data sets as discussed in Chapter 3.

The Sentinel Initiative has successfully piloted safety surveillance utilizing a distributed data model that uses primarily administrative claims data[116] and may be suitable for Tier I data. CMS is developing a model of using EHR data for quality measurement that might be suitable for surveillance. Further, with the growth of EHRs and data models designed for EHRs, MDS should develop data models that can be used in conjunction with direct queries of the medical record for more in-depth safety surveillance.[117] For Tier II, data models that enable the linkage of data from established device registries with administrative claims data submitted to meet other reporting requirements, such as Qualified Clinical Data Registries (QCDRs),[112] could support longitudinal data collection and analyses.[118] For Tier III, the current paradigm for in-depth, rigorous studies relies on access to primary clinical data and, in turn, substantial standard data submission requirements.[119] The model that is best suited for basic safety surveillance is likely to be insufficient for detailed clinical effectiveness studies. The Planning Board recommends that the implementation of MDS include the adaptation of existing data models to support these activities.

Developing Analytical Tools

MDS success will depend upon continued advancements in analytic methods and tools to generate reliable information. MDS will need to develop more standardized and efficient ways to utilize different types of complex data from heterogeneous sources, and addressing the potential for selection bias and confounding when utilizing observational data from non-randomized patients receiving routine clinical care.

MDEpiNet has been at the forefront of recent efforts to support the development of new methods and analytical tools for medical device surveillance.[120,121] It has also led efforts to identify and assess common methodological challenges such as treatment effect heterogeneity, confounders adjustment, missing data, signal detection, and inter-operator variability,[122] and piloted the first successful example of device-specific automated safety surveillance.[123] Many of these tools will require patient-level data assembled together, rather than a distributed data model.

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The Reagan-Udall Foundation's IMEDS Program is also committed to developing better methods and tools for drug and vaccine postmarket safety surveillance. The program has supported development of methods used in FDA's Mini-Sentinel pilot program,[124] and could also be leveraged to support active surveillance activities relevant to devices. The Planning Board recommends the system look to these and other programs that are leading the effort in methods development to take advantage of what is currently available, and to work collaboratively to make advancements in this important area.

Developing Methods for More Reliable Data Capture of Key Device-Related Events

Many devices require regular monitoring and maintenance as a part of appropriate patient care. It is important to differentiate regular device maintenance from adverse events. Current claims coding systems do not identify when or why a medical device has been removed, repaired, or upgraded. There are also currently few validated tools to extract these types of data from EHRs. Unfortunately, this information is also not to be addressed by the coming upgrade to ICD-10.[125]

A possible solution is to explore the development of additional data sources that explicitly identify regular anticipated maintenance (e.g., prosthesis has been in for full length of time allowed), maintenance that is not anticipated, device/implant failures (e.g., loss of function, breakage), and complications (e.g., erosion, loss of insulation, fragmentation). Better understanding of how devices are monitored as a regular part of care could inform the ongoing assessment of their safety and effectiveness. It could also support better clinical care. One data source could be a coding system that differentiated safety and quality issues in device care, as opposed to routine device/implant-related care. However, any change to the coding systems are challenging and require significant lead time and broad stakeholder buy-in, with engagement with health plans (who may need such information for quality measurement and payment purposes), as well as with physicians in the relevant specialties (e.g., orthopaedics, cardiology). There are also other data sources, including from the manufacturers who are streaming data from some devices and from patients themselves through patient-reported outcome measures.

C. Creating Value for Patients and Other Stakeholders

As noted in the previous chapters, MDS will need to offer valuable services to a broader group of stakeholders beyond FDA if it is to be viable and sustainable. During both the incubator project and subsequent system implementation, there will need to be an ongoing assessment of the functional and financial value the system provides to participating stakeholders.

Patient Value

Central to both the successful implementation and sustainability of MDS will be the value the system creates for patients. MDS leadership should engage with patients to ensure that system activities focus on outcomes and information they need to make informed decisions about their health. MDS should support efforts to better communicate timely, reliable, and understandable information about devices to patients. This information can help inform clinical decisions.

MDS should also work with partners to build standards and identify best practices for the development, validation, and utilization of patient-generated data about the safety and effectiveness of medical devices. For example, patients can report adverse events, and provide valuable information about their experiences with medical devices either through their clinicians or other mechanisms. As part of a patient-focused system, patients should be active participants in these activities.

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Clinician Value

Clinicians are primarily interested in achieving positive outcomes for their patients, but are also seeking ways to reduce the reporting and other administrative burdens they face in practice today. MDS activities should support generating practical evidence on device performance to achieve better outcomes in ways that reduce reporting burdens compared to those faced by clinicians today.

Clinicians also struggle with the increasing demands to collect clinical information for a variety of uses. MDS should work with other evidence development activities to identifying tools to support more automated data collection from clinical systems, patient tracking systems, and minimizing existing surveillance requirements being implemented by health plans and FDA to monitor performance of major medical devices. Improving the quality and timeliness of clinical information should lead to improvements in patient care. MDS should work with FDA and manufacturers to quickly and accurately provide clinicians with information about potential safety problems.

Medical Device Industry Value

Manufacturer support is also important for the success of MDS. While manufacturers share an interest in and also benefit from better, timelier information on device performance, pilots should have a clear plan for how they will provide manufacturers with a more effective, reliable, and cost-efficient mechanism to monitor for device safety and effectiveness. Pilots should be able to demonstrate how they will permit more rapid and reliable evaluation of potential safety signals. MDS pilots should work to provide a foundation for manufacturers to conduct further safety and effectiveness studies. For example, pilots that link better information on device performance with patient demographic and clinical information could support conduct of longitudinal clinical studies to assess products' benefits and risks, evaluate outcomes in different subpopulations, and identify potential product refinements. Pilots may also be able to demonstrate how they can help support innovation (e.g., by providing more complete and timely feedback on opportunities for product improvement). Finally, MDS activities should work to demonstrate to FDA and the public that evidence generated through the system is more reliable, accurate, and timely than the current reporting requirements (e.g., MDRs). Once this goal is achieved, it may be possible to explore how to shift reporting requirements to reduce the burden of data collection to meet postmarket surveillance requirements.

Data Partner Value

Implementation of the MDS infrastructure will require support for health care organizations, health plans, and other entities that hold data related to clinical care. Many health plans and some health care organizations have already developed business models that use internal data to evaluate utilization and clinical outcomes. Currently, most of these efforts are focused on pharmaceuticals. MDS should seek to build off of these efforts to build the capacity to capture devices. MDS efforts to expand the capabilities of individual data partners (e.g., health plans and health care organizations) to capture device-specific information not only improves their internal data partner systems, but also creates the ability for them to participate in external efforts. For example, MDS could support pilots that help data partners capture UDIs at a lower cost or more efficiently. Data partners could then participate in MDS to address surveillance questions that cannot be answered by individual partners alone and support information about potential safety problems earlier to their providers.

Health care organizations (e.g., hospitals, ambulatory surgical centers, and other providers) are also increasingly being asked to provide supplemental information on costly and higher-risk devices, especially implantable devices, as a condition for payment. MDS should support efforts to reduce the burden and improve the accuracy of data collection for health care organizations.

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Public Sector

MDS should identify activities that support the needs of other public sector agencies such as NIH, CMS, and AHRQ. Potential activities could be piloted to demonstrate their value and feasibility. For example, pilots could provide new information on clinical populations to help guide further clinical research questions and improve the design of clinical studies. Some pilots could leverage CMS interest and activities related to evidence on the clinical effectiveness of medical devices. In particular, one or more pilots could help develop a better capacity for CMS to conduct Coverage with Evidence Development (CED) activities on medical devices at a lower cost, and could use CED data for key device surveillance purposes. Pilots could also give CMS better empirical evidence to help make determinations about when the benefits of CED outweigh the harms, and how CED should be conducted.

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APPENDIX A
Pilot Concepts to Initiate the Development of the MDS Data Infrastructure

As discussed in Chapter 4, the best way to illustrate the short-term steps needed to develop MDS is to initiate a small number of well-designed, high-impact pilot activities assessing the feasibility of certain approaches. In this final section, the Planning Board proposes three pilot concepts that could inform the Incubator Project's five-year implementation plan. Successful implementation or completion of these activities would demonstrate how key challenges to device surveillance can be overcome, reduce costs, and provide valuable evidence on major medical devices for patients and other stakeholders.

Pilot Concept 1: Clinical Data Systems Supporting Device Safety Surveillance

TECHNICAL CHALLENGES:

- Efficient adoption of UDIs within clinical care systems used by a range of hospitals
- Effective mechanisms for providing key device data from hospital clinical systems to external clinical registries
- Sustainable registries for device surveillance through lower-cost, timely integration of needed data
- Linking key device information to the Sentinel system to enable effective longitudinal, claims-based device surveillance

PILOT GOAL:

- Scaling UDI adoption in health systems and demonstrating the feasibility of linking with national registries and the Sentinel system for enhanced device surveillance

Pilot Objectives:

- Implement a standardized UDI EHR prototype in multiple health care systems (e.g., Mercy Health prototype)
- Develop a distributed network of UDI-based device data among partners
- Link the sites to integrate local data to national clinical outcomes registries

Pilot Outcome:

- Implement a generalizable and scalable approach for linking primary clinical sites directly with registries as proof-of-concept for data aggregation and analyses to support device surveillance

Overview:

Some health care organizations have already begun to implement UDIs into their EHR systems, albeit with different levels of readiness and adoption. This pilot will expand on the efforts led by early adopters to link UDIs captured at the point-of-care to one or more national device registries to provide enhanced device surveillance capabilities. For example, Mercy Health adopted UDIs into their EHR system. Mercy is a member of the Healthcare Transformation Group (HTG) clinical partners (e.g., Geisinger, Intermountain Healthcare, Kaiser Permanente, and Mayo Clinic), all of which have expressed interest in UDI adoption and participation in device surveillance. Other health care organizations may also be interested in participating. The pilot would develop standard practices and tools for implementing the UDI system in EHRs in the other health care systems, and then link all sites to a national clinical registry. This would enable efficient and more effective surveillance of important outcomes associated with high-risk implantable devices. Other participants

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in the pilot could include partners from device manufacturers, FDA, clinicians, academics, information technology professionals and EHR vendors, and supply chain personnel.

A further extension of this pilot could include linking UDI and clinical outcomes data from these sites to the Sentinel distributed data system, in order to enable a more comprehensive evaluation of short- and longer-term outcomes. Such a pilot extension could have the following objectives:

- Identifying administrative and claims data elements to include in the Sentinel common data model
- Create an algorithm for health systems to identify patients exposed to high-risk medical devices to additional outcomes that can be measured within the Sentinel Data system

Pilot Concept 2: Development of Tools for Routine Surveillance of Implantable Device Safety

TECHNICAL CHALLENGES:

- Extracting a limited number of device-related data elements from EHRs to support basic safety surveillance
- Reducing data collection burden for key data elements needed for basic safety surveillance

PILOT GOAL:

- Adopt and adapt a common data model, based on clinical data extracted from EHRs or other electronic systems at the site of surgical implant of high-risk devices, that could form the core data set for device surveillance

Pilot Objectives:

- Test the feasibility of extracting a small core set of device-related data elements from EHRs
- Identify a small core set of extractable EHR and administrative data to support primary safety surveillance activities

Pilot Outcome:

- Develop a generalizable and scalable approach for extracting a core data set from EHRs to enable data aggregation and analyses to support device surveillance

Overview:
A limited number of data elements for some types of major implantable devices, if collected routinely, could provide a substantial enhancement to current device safety surveillance capabilities. These core data elements may differ based on the therapeutic area or device type. While the initial dataset would be limited to minimize collection burden, a well-designed core dataset could provide critical "early warnings" about potential safety problems and thus be of significant value to patients, clinicians, manufacturers, and payers. The limited dataset could also provide a foundation for building out a more extensive national-scale safety surveillance capacity. The pilot would need to:

- Identify candidate data elements
- Determine if the data elements are captured in EHRs, administrative data systems, or other electronic data systems across a wide range of settings,
- Develop tools to obtain and integrate the data elements to form a basic safety surveillance capability

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This pilot concept is similar to a recent CMS-funded study.[117] In the CMS study, once identified, the dataset was used and shown to be effective for real-world analyses. The proposed pilot could apply a similar approach to develop and explore the utility of a core dataset for medical device postmarket safety surveillance.

Additionally, there may be several characteristics of the device and provider setting to take into consideration. The new pilot should build upon work by other groups to identify candidate core data elements. For example, the American Joint Replacement Registry (AJRR) has identified and pilot tested a set of data elements for quality measurement of total hip and knee replacement procedures that may be a valuable reference for this work. AJRR's core elements include data from EHRs, administrative claims system, and existing orthopaedic registries:

- Patient data: Name, sex, date of birth, social security number, ICD-9 code for diagnosis
- Surgeon data: Name, number of surgeries performed
- Procedure data: ICD-I code for type of surgery, date of surgery, patient age at surgery, laterality, implant
- Hospital data: Name, address, number of surgeries performed there

The pilot should seek to leverage existing methods and analytical tools for medical device safety surveillance. The pilot should be integrated with existing work in postmarket surveillance, such as MDEpiNet and IMEDS. The tools developed by MDEpiNet in the DELTA network study may be valuable starting point.

A second phase of this pilot could begin to identify scalable strategies for linking this core dataset to a more comprehensive set of patient characteristics and outcomes data obtained from distributed data partners, including payers, other provider systems, and registries, utilizing an expanded common data model.

PILOT 3: Implantable Device Surveillance Using Patient-Reported Information

TECHNICAL CHALLENGE:

- Collecting data on patient outcomes and experiences throughout the product lifecycle

PILOT GOAL:

- Leverage existing efforts to develop a process for including patient-generated data and patient perspectives and priorities in the developing device surveillance system, for example in hip and knee replacement

Pilot Objectives:

- Implement and refine existing tools to allow clinical sites to report validated patient outcome measures
- Develop tools to allow patients to report validated patient outcome measures
- Develop a process of including patient perspectives within system priorities

Pilot Outcome:

- Implement a set of scalable tools to capture patient perspectives and patient-generated data in the postmarket evaluation of medical devices

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Overview:
The Medical Device Innovation Consortium (MDIC) is currently developing a catalog of methods available to collect information on patient preferences and a framework for thinking about in what situations and how patient preference information might be collected and used in CDRH regulatory decisions. These include, for example, tools that have begun to be used in orthopaedic registries for tracking outcomes after joint replacement surgery. It is possible that these measures and tools could be repurposed to also support postmarket evidence development on medical devices. This would support the concept of balancing evidence development throughout the product's lifecycle. The NIH Patient Reported Outcomes Measurement Information System (PROMIS) may also be a key stakeholder for this pilot because of their expertise in developing and validating assessments of patient-reported health outcomes.

A potential pilot could partner with PCORI's PCORnet research networks. In PCORnet's Patient-Powered Research Networks (PPRN), which comprise patients and/or caregivers who participate in patient-generated health care research, PPRN members share their data and take part in research studies. PCORnet's Clinical Data Research Networks (CDRN) are working to develop the capacity to conduct comparative effectiveness research using EHR and claims data. Some health systems have begun to adopt tools for capturing patient functional outcomes after surgery in their EHRs. A pilot could both test the collection of these measures in CDRNs, and utilize the PPRN's patient portals to allow patients and caregivers to directly report these measures. The pilot would also seek to use any associated registries (e.g., hip and knee implant registries) for device surveillance.

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APPENDIX B
Planning Board Membership Biosketches and Selection Criteria

I. The National Medical Device Postmarket Surveillance System Planning Board Members Biographical Sketches

Kathleen Blake, MD, MPH, is Vice President for Performance Improvement at the American Medical Association and Executive Director of the AMA-convened Physician Consortium for Performance Improvement® (PCPI®), which includes among its activities the National Quality Registry Network™ (NQRN™). Dr. Blake is responsible for ensuring the successful execution of all components of the PCPI strategic direction and the integrity of its measure portfolio. She is a member of the HIT Policy Committee Quality Measures Workgroup of the Office of the National Coordinator for Health Information Technology, the FDA-sponsored National Medical Device Postmarket Surveillance Planning Board, the Medical Device Epidemiology Network Council, and the PCORI Dissemination and Implementation Stakeholder Council. She has previously represented the Heart Rhythm Society (HRS) in the AMA House of Delegates and the PCPI and on the PCPI Work Group on congestive heart failure performance measures. As chair of the HRS Health Policy Committee, she led a team of physician volunteers and staff to address policy issues at the federal level and was a Founding Co-Chair of the Society's Measure Development Task Force. Prior to coming to AMA, Dr. Blake was Senior Research Director at the Center for Medical Technology in Baltimore, Maryland, overseeing Public-Private Partnerships, Policy and Education and serving as an advisor to the American Joint Replacement Registry and National Radiation Oncology Registry. Dr. Blake is a clinical cardiac electrophysiologist who earned her medical degree from the University of Chicago, followed by post-doctoral training in internal medicine and cardiovascular diseases at Stanford University. From 1988 until 2011, Dr. Blake practiced at the New Mexico Heart Institute, where she also served as President. In 2011, she earned a Master of Public Health degree from the Johns Hopkins Bloomberg School of Public Health.

R. Michael Crompton, JD, MPH, RAC, is the Vice President, Regulatory Affairs & Quality Assurance / Chief Compliance Officer at ReVision Optics, Inc., a start-up company developing novel technologies to address presbyopia. He has more than 25 years of experience in the medical device industry. His tenure in the medical device industry has included roles as the Vice President, Regulatory/Clinical Affairs & Quality at Micrus Corporation, an innovative neurological device company, Chief Compliance Officer and Vice President, Regulatory/Clinical Affairs & Quality Assurance at Carl Zeiss Meditec, Inc., a large multi-national ophthalmic diagnostic and therapeutic medical device company, as well as vice president at two start-up medical device companies which developed and commercialized novel medical technologies in otolaryngology and interventional cardiology. Prior to returning to the medical device industry, Mr. Crompton was an attorney at Hyman, Phelps & McNamara, the largest dedicated Food and Drug law firm in the United States. He is a member of the Regulatory Affairs Professionals Society and is RAC certified. He holds a Bachelor's degree in biochemistry and a Master's degree in public health (biomedical sciences) from the University of California at Berkeley. He earned a doctorate in jurisprudence from the University Of San Francisco School Of Law and is a member of the State Bar of California.

Jodi G. Daniel, JD, MPH, has served as Director in the Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS), since October 2005. She is responsible for thought leadership, policy development, and identifying policy levers for health information technology (health IT) activities including, establishing new policies and working with other federal agencies and private organizations to coordinate efforts regarding adoption and health information exchange. Ms. Daniel leads strategic initiatives regarding emerging issues in health care and technology, including consumer engagement using new technology (e.g., gaming, social media, mHealth), health IT safety (including clinical

decision support, usability, and safety oversight), personalized medicine, and big data. She leads ONC's regulatory activities to develop standards and certification criteria for electronic health records and to establish a governance mechanism for nationwide health information exchange. She also considers legal and ethical issues regarding health IT, such as liability, fraud and abuse laws, and patient access to information. Ms. Daniel manages ONC's federal advisory committees, which provide advice on all health IT policy and standards related matters, and developed the Federal Health IT Strategic Plan. Ms. Daniel developed HHS's foundational legal strategies for health IT, as the first Senior Counsel for Health Information Technology in the Office of the General Counsel of HHS. She founded and chaired the health information technology practice group within OGC and worked closely with the Centers for Medicare and Medicaid Services in the development of thee-prescribing standards regulations and the proposed Stark and anti- kickback rules regarding e-prescribing and electronic health records. Ms. Daniel earned a law degree from Georgetown University and a Masters in Public Health from Johns Hopkins University.

Nancy Dreyer, PhD, MPH, is Global Chief of Scientific Affairs for Quintiles Real-World & Late Phase Research. She has more than 30 years of experience in the design, conduct and interpretation of epidemiologic research. She heads a team of researchers who conduct and interpret population-based research on comparative effectiveness and safety, and outcomes research. Some of her recent high profile activities include serving as a senior editor of two User's Guides for the US Agency on Healthcare Research and Quality, "Registries for Evaluating Patient Outcomes," now in its third edition, and "Developing a Protocol for Observational Comparative Effectiveness Research". Both of these books have been published in Chinese, and the registries book has also been adapted in Korean. Dr. Dreyer is co-lead investigator with the European Medicines Agency for a study on developing new methodologies for pharmacovigilance using direct-to- consumer data collection. She also leads the GRACE Initiative which is developing guidance on Good Research Practices for Observational Studies of Comparative Effectiveness (www.graceprinciples.org). Dr. Dreyer is an Adjunct Professor of Epidemiology at the University of North Carolina at Chapel Hill, a Fellow of the International Society of Pharmacoepidemiology, and is a member of the Academic Consulting Committee at the Center of Postmarketing Safety Evaluation at Peking University Health Science Center. Prior to joining Quintiles, she was CEO of Epidemiology Resources, Inc. for 20 years, where she founded the peer-reviewed journal, *Epidemiology*.

Joseph P. Drozda, Jr., MD, FACC, is a cardiologist and Director of Outcomes Research at Mercy—a four-state regional health system. He is a member of the American College of Cardiology Board of Trustees, chairs the ACC's Clinical Quality Committee, is a member of the National Cardiovascular Data Registry (NCDR) Management Board, and represents ACC at NQF. He chairs the Measures Advisory Committee and sits on the Executive Committee of the AMA's Physician Consortium for Performance Improvement. He was VP Medical Management for SSM Health Care—the first healthcare organization to receive the Malcolm Baldrige award—and was a managed care executive for 25 years. He has been involved in clinical quality improvement efforts and research for more than 25 years. He has been active in developing practice guidelines, disease management programs, and performance measures co-chairing the PCPI multi-society workgroups that developed measures in congestive heart failure, coronary heart disease, hypertension, and stroke and stroke rehabilitation. His group at Mercy recently completed a demonstration for FDA on incorporation of Unique Device Identifiers into Mercy information systems resulting in the creation of a database containing clinical and device information for purposes of surveillance and research. The demonstration was presented with a Mercy Innovation Award and the Intelligent Health Association's 2014 Best Use Case Award. He leads a research team from five major U.S. health systems developing an extension of the Mercy demonstration that will result in the creation of a distributed data network using the NCDR as its hub.

Rachael L. Fleurence, PhD, is the Program Director for CER Methods and Infrastructure at the Patient-Centered Outcomes Research Institute (PCORI) where she has been since April 2012. Under this remit, she is responsible for PCORI's program to set up the National Patient-Centered Clinical Research Network, or

PCORnet. She is also responsible for leading PCORI's Methods program. A health economist and health services researcher by training, prior to PCORI, Dr. Fleurence worked in the field of health outcomes and comparative effectiveness research and was a senior leader at United BioSource Corporation where she led outcomes research teams. Dr. Fleurence received a BA from Cambridge University (United-Kingdom), a MA in business management from ESSEC-Paris (France), and a MSc and PhD in health economics from the University of York (United-Kingdom).

David R. Flum, MD, MPH, is a gastrointestinal surgeon and outcomes researcher at the University of Washington. He holds the rank of Professor in the Schools of Medicine, Public Health, and Pharmacy, and serves as the Director of the Surgical Outcomes Research Center (SORCE) and Associate Chair for Research in the Department of Surgery. He earned a Master's Degree in Public Health in the field of health services research while in the Robert Wood Johnson Clinical Scholars Program at the University of Washington. Dr. Flum is an internationally recognized surgical epidemiologist and outcomes researcher—a leader in bridging clinical care and public health issues. His work is aimed at improving health care by studying the impact of interventional care by identifying processes of care that work helping increase their use. Dr. Flum serves as the Program Director of the NIDDK-funded, post-doctoral T32 training program in surgical outcomes research and is Principal Investigator for several research studies evaluating the mechanisms, impact and/or outcomes of surgery on obesity and diabetes. He is Medical Director of CERTAIN, a patient-centered research network focused on conducting comparative studies of health care treatments and technology. Dr. Flum also was the founder and Medical Director (2005-2011) and currently serves as Research and Development Lead of the Surgical Care and Outcomes Assessment Program (SCOAP), a quality of care improvement program providing hospital-specific data feedback and best practices regarding processes of care and outcomes to more than 55 Washington State hospitals. He sits on the editorial boards of Surgery and the British Journal of Surgery and was Chair of the American College of Surgeons' Surgical Research Committee from 2008 to 2013. In 2011, Dr. Flum was appointed to the Methodology Committee of the federal Patient-Centered Outcomes Research Institute (PCORI).

Thomas P. Gross, MD, MPH, is currently the Director of the Office of Surveillance and Biometrics at the Center for Devices and Radiological Health of the Food and Drug Administration. Prior to coming to FDA in the late 1980s, Dr. Gross worked as an Epidemic Intelligence Service Officer with the Centers for Disease Control and Prevention and earned a Master of Public Health degree from the Johns Hopkins School of Hygiene and Public Health. He also served in the Commissioned Corps of the U.S. Public Health Service (Captain, retired) and is board certified in Pediatrics, General Preventive Medicine, and Clinical Pharmacology.

Leslie Kelly Hall is the Senior Vice President Policy for Healthwise. Ms. Hall is widely recognized as a leader in health care information technology. As a health system CIO and marketing officer, her achievements have made a significant impact in Idaho health care. She created Idaho's first physician portal and patient portal and was the driving force behind the development of the Idaho Health Data Exchange. In 2004 her efforts were recognized by *Business Week* as one of the top 50 Web Smart leaders in the country. Ms. Hall was appointed by HHS Secretary Sebelius to the Health Information Technology Committee, where her efforts have expanded to: Chair, Patient Engagement Team, member Meaningful Use Committee; Privacy and Security Standards Committee, and recently part of the Patient Access Summit at the White House.

Jo Carol Hiatt, MD, MBA, FACS, is Chair of the National Product Council for Kaiser Permanente and also chairs KP's Inter-Regional New Technologies Committee. She is a partner in Southern California Permanente Medical Group (SCPMG) and is currently Assistant Medical Director, SCPMG Business Management. Dr. Hiatt chairs Southern California's Technology Deployment Strategy Team as well as the Oversight Committee for Integrated Medical Imaging. Dr. Hiatt joined Kaiser Permanente as a general surgeon at Panorama City, later serving as Chief of Surgery at that location and member of the SCPMG Board of Directors. Dr. Hiatt received

her undergraduate degree from Stanford University and her medical degree from Duke University. She trained in general surgery at UCLA. In addition to her clinical degree, Dr. Hiatt received an M.B.A from UCLA's Anderson School of Management. She was designated an American College of Surgeons Health Policy Scholar in 2013.

Ira Klein, MD, MBA, F.A.C.P., *(August 2014-December 2014)* is the National Medical Director in the Office of the Chief Medical Officer, holding the position of Clinical Thought Leadership, responsible for core program development across the enterprise at Aetna. He recently transitioned from his previous role of almost two years as Chief of Staff to the Chief Medical Officer, having been in this role since 2011, and remains as part of the team responsible for communicating and deploying the strategic efforts of the CMO in multiple areas, including leveraging of business acquisitions, and clinical integration and clinical program development. He joined Aetna in 2006 as a Medical Director in the Northeast Region. In 2009, he transitioned to the corporate-level National Accounts Sales and Support group, where he was involved in the development of new benefits designs, financial and clinical analytics for National Accounts, and the evolution of oncology strategies. Prior to joining Aetna, Dr. Klein was the Medical Director for Quality and Case Management at Bayshore Community Health System in New Jersey. Before that, he also served as the Chief Medical Officer of Elderplan, an 11,000-member Medicare Social HMO that focused on the frail elderly. Ira is a clinical assistant professor of medicine at the University of Medicine and Dentistry of New Jersey – Robert Wood Johnson Medical School and participates in numerous professional organizations including the Association of Health Insurance Plans, the American College of Physicians and the Medical Society of New Jersey. His honors include Alpha Omega Alpha membership since medical school, receiving the Master Clinician Teaching Award, Physical Diagnosis Program, from the Robert Wood Johnson Medical School and being elected as Fellow of the American College of Physicians. Dr. Klein received his B.S. in Pharmacy, and an M.B.A. from Rutgers University, and his medical degree from the University of Medicine and Dentistry of New Jersey – Robert Wood Johnson Medical School, all with highest honors. He completed his residency in internal medicine at Brown University and Robert Wood Johnson University Hospital.

Harlan M. Krumholz, MD, SM, is the Harold H. Hines, Jr. Professor of Medicine and Director of the Yale-New Haven Hospital Center for Outcomes Research and Evaluation (CORE). He is also a Director of the Robert Wood Johnson Foundation Clinical Scholars Program at Yale University School of Medicine. His research focuses on improving patient outcomes, health system performance and population health. His work has had wide-ranging impact on health care delivery, shifting paradigms of clinical care, and increasing the accountability of the health care system through the application of targeted measurements, incentives, and improvement strategies. Some of the accomplishments include reductions in delays associated with lifesaving heart attack care, increases in the use of guideline-endorsed treatments of patients requiring acute and chronic care, identification and elimination of wasteful health care practices, and improvements in the outcomes of patients recently discharged from the hospital. In addition, his work has focused attention on the importance of patient-centered care. He is currently working with leaders in China on government-funded efforts to establish a national research and performance improvement network. Dr. Krumholz is an elected member of the Institute of Medicine, the Association of American Physicians, and the American Society for Clinical Investigation. He is a Distinguished Scientist of the American Heart Association. He serves on the Board of Trustees of the American College of Cardiology, the Board of Directors of the American Board of Internal Medicine, and the Board of Governors of the Patient-Centered Outcomes Research Institute. He received a BS from Yale, an MD from Harvard Medical School, and a Masters in Health Policy and Management from the Harvard University School of Public Health.

Michael Mack, MD, has practiced cardiothoracic surgery in Dallas, TX since 1982. He is board certified in Internal Medicine, General Surgery, and Thoracic Surgery and is currently the Director of Cardiovascular Surgery for the Baylor Scott & White Health, Chair of the Baylor Scott & White Health Cardiovascular Governance Council and Director of Cardiovascular Research at The Heart Hospital Baylor Plano. He also co-

founded and is Chair of the Board of Cardiopulmonary Research Science and Technology Institute (CRSTI). He has more than 400 peer-reviewed medical publications. Dr. Mack was President of the Society of Thoracic Surgeons (STS) 2011 and is Past President of the Thoracic Surgery Foundation for Research and Education (TSFRE) 2009-2011, the Southern Thoracic Surgical Association (STSA) 2009 and the International Society for Minimally Invasive Cardiothoracic Surgery (ISMICS) 2000. He has served on the Board of Directors of the STS and is currently on the Board of Directors of CTSNet, and is a member of the American College of Cardiology Foundation (ACCF) Board of Trustees and the ACC Interventional Scientific Council. He is an honorary Fellow of the German Society for Thoracic and Cardiovascular Surgery and the Indian Association of Cardiothoracic Surgery. He was the first Chair of the STS/ACC National Transcatheter Valve Therapy (TVT) Registry Steering Committee and is the liaison to the TVT Registry from the ACCF National Cardiac Data Registry (NCDR) Management Board and is on the Steering Committee of the Cardiothoracic Surgery Network (CTSN) of the NIH. He is a member of the FDA MDEpiNet Advisory Committee, the NCDR Management Board and the National Medical Device Postmarket Surveillance System Planning Board.

Matthew McMahon, PhD, coordinates the translation of basic science discoveries into ophthalmic drugs, diagnostics, and medical devices as director of the NEI Office of Translational Research. The office identifies emerging opportunities to advance small molecules, gene- and cell-based therapies, medical devices, and other novel therapeutics through public-private partnerships with the pharmaceutical and biotechnology industries. Dr. McMahon completed his graduate studies in retinal structure, function, and visual perception at the University of California, San Diego and postdoctoral training in primate retinal physiology at the University of Washington. He then served for five years as senior principal scientist for the retinal prosthesis company Second Sight Medical Products. In 2009, Dr. McMahon moved to Capitol Hill as an AAAS Science and Technology Policy Fellow for the Senate Committee on Commerce, Science, and Transportation. He then served as professional staff on the House Science and Technology Committee, where he oversaw innovation, manufacturing, technology transfer, and bioscience policy.

Dale Nordenberg, MD, is a principal with Novasano Health and Science. He is a physician executive that leverages his experience as a pediatrician, medical epidemiologist, and informatician to deliver strategic, operational, and scientific services to clients in the health care and health information technology arena. Clients include both private and public sector institutions that are engaged in challenging activities such as new operational or business model development, novel information infrastructure development, collaborative/open innovation activities that are dependent on complex information supply chains, and the development of funding strategies. From 2002 through 2007, Dr. Nordenberg held various positions at CDC including Associate Director and Chief Information Officer (CIO), National Center for Infectious Diseases (NCID), and Senior Advisor for Strategic Planning, Office of the CIO, CDC. During this time, Dr. Nordenberg led the development of the CDC's agency-wide IT strategic plan (2008–2012) and he was responsible for informatics for the agency's infectious disease center where he initiated the implementation of a single laboratory platform for NCID's labs and launched the Public Health Laboratory Interoperability Project (PHLIP) in collaboration with the Association of Public Health Labs to create a standards-based national laboratory data sharing network. Prior to CDC, Dr. Nordenberg was a founding executive of a company that launched VeriSign affiliates in Latin America and Asia and prior to that he was faculty in the Emory School of Medicine where he founded and directed the Office of Medical Informatics for the Emory University Children's Center. Dr. Nordenberg is a board-certified pediatrician. He received a BS in Microbiology from the University of Michigan, his medical degree from Northwestern University, completed his training in pediatrics at McGill University, Montreal Children's Hospital. He completed his fellowship in epidemiology and public health in the Epidemic Intelligence Services Program at the CDC.

J. Marc Overhage, MD, PhD, is the Chief Medical Informatics Officer for Cerner Health Services (formerly Siemens Healthcare). Prior to joining Cerner he was the founding Chief Executive Officer of the Indiana Health Information Exchange and was Director of Medical Informatics at the Regenstrief Institute, Inc., and a Sam Regenstrief Professor of Medical

Informatics at the Indiana University School of Medicine. He has spent more than 25 years developing and implementing scientific and clinical systems and evaluating their value. Over the last decade, Dr. Overhage has played a significant regional and national leadership role in advancing the policy, standards, financing and implementation of health information exchange. He served on the National Committee for Vital and Health Statistics and the Health Information Technology Standards Committee as well as serving on the Board of Directors of the National Quality Form and being engaged in a number of national health care initiatives. He practiced general internal medicine for more than 20 years including the ambulatory, inpatient and emergency care settings.

Edmund Pezalla, MD, MPH, serves as National Medical Director for Pharmaceutical Policy and Strategy for Aetna in the Office of the Chief Medical Officer. He was previously the Head of Clinical Services for Aetna Pharmacy Management from 2007 to 2009. Prior to Aetna, Dr. Pezalla was the Vice President and Medical Director for Clinical Services at Prescription Solutions, now Optum Rx, 2004–2007. He has also served as Head of Clinical Science for Pfizer Health Solutions, 1996–2001, and was Chief of Pediatrics at the Kaiser Permanente Medical Center in Fremont, California from 1991 to 1995. He received his medical degree from Georgetown University and completed a flexible internship and pediatric residency at The Bethesda Naval Hospital. He received his MPH from the University of California at Berkeley in 1995 and was a health services research fellow and post-doctorate fellow in health policy at the University of Michigan, 2001–2003.

Gurvaneet Randhawa, MD, MPH, *(August 2014–Present)* is a medical officer and is a Senior Adviser on Clinical Genomics and Personalized Medicine. He is a past director of the U.S. Preventive Services Task Force (USPSTF) program. Prior to joining AHRQ in 2002, he completed his Preventive Medicine residency at Johns Hopkins University and his Internal Medicine internship at University of Pennsylvania. He also trained for nine years in biomedical research at Johns Hopkins at Baltimore, Maryland and M.D. Anderson Cancer Center at Houston, Texas. His research was in cancer molecular genetics and also on genomic applications in tuberculosis control. He was the lead author of four American Recovery and Reinvestment Reinvestment Act-–funded request for applications that collectively built a national clinical electronic data infrastructure, and advanced the methods to collect and analyze prospective, patient-centered outcomes data for comparative effectiveness research (CER) and for quality improvement (QI). He was the program official for all 12 grants that comprised 4 programs: scalable distributed research networks, enhanced registries for QI and CER, Prospective Outcome Systems using Patient-specific Electronic data to Compare Tests and therapies (PROSPECT), and the Electronic Data Methods Forum. He has previously worked with AHRQ's Developing Evidence to Inform Decisions about Effectiveness (DEcIDE), Centers for Education and Research on Therapeutics (CERTs), and the Evidence-based Practice Centers (EPC) programs. He provided scientific direction to two successive DARTNet projects, which successfully created a new distributed research network in ambulatory care, and evaluated its use for CER in diabetes and depression, respectively. He provided direction to a project that developed a new clinical decision support tool for BRCA tests in primary care practice to implement USPSTF recommendations. The tool has been adapted for use by the Centers for Disease Control and Prevention (CDC). He has authored numerous publications, serves as a peer-reviewer for scientific journals, and served in several committees, including the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), steering committee of Evaluation of Genomic Applications in Practice and Prevention (EGAPP), and steering committee of the National Patient-Centered Clinical Research Network (PCORnet).

Alan Rosenberg, MD, is Vice President of Clinical Pharmacy and Medical Policy for Anthem and President of its subsidiary Anthem UM Services, Inc. His experience includes one of looking at the efficacy and effectiveness of drugs, devices, and procedures. He is a Fellow of the Institute of Medicine of Chicago, a member of the Blue Cross Blue Shield Medical Policy Panel, and America's Health Insurance Plan's CMO Committee, and serves as a Board Member of URAC and the National Headache Foundation. He received a BA from Columbia University and MD from New York University, completing his residency at the University of

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Chicago's Michael Reese Hospital, and he is Board Certified in Internal Medicine. He serves on PCORI's advisory panel on Prevention Diagnosis and Treatment. In addition he serves on advisory boards for University of California, San Francisco Translating Personalized Medicine program, The Center for Medical Technology Policy, and Green Park Collaborative, USA. He also served on the Agency for Health Research and Quality Effective Health Care Program Stakeholder Group.

Pat Shrader, JD, is Vice President of Global Regulatory Affairs Medtronic, Inc., a position she has held since April 2011. In this role, Ms. Shrader leads the Regulatory Affairs function for the company, developing and implementing a regulatory strategy designed to meet Medtronic's overall short and long-term business goals and objectives globally. She serves as the primary company representative interacting with regulatory authorities across the globe to proactively influence regulatory policy and to respond to regulatory issues. She leads the Corporate Regulatory Affairs department and the global regulatory affairs leadership council. Pat was a founder of the In Vitro Diagnostics Roundtable, an FDA and industry group. She participates in the Advanced Medical Technologies Association as co-chair of the Technology and Regulatory Working Group, is Regulatory Affairs Certified and is a board member of the Food and Drug Law Institute. She also sits on the Board of Directors of AAMI (Association for the Advancement of Medical Instrumentation) and is a member of the AdvaMed Research Council. She is a graduate of Georgetown University Law Center and is a member of the bars of Pennsylvania, Maryland, and the District of Columbia.

Tamara Syrek Jensen, JD, is the deputy director for the Coverage and Analysis Group (CAG) at the Centers for Medicare & Medicaid Services (CMS). CAG develops, interprets, communicates, and updates evidence-based national coverage policies. These policies help provide timely access to reasonable and necessary services and technologies to improve health outcomes for Medicare beneficiaries. Before her current position at CAG, she was the Special Assistant for the CMS Chief Medical Officer and Director of the Office of Clinical Standards and Quality (OCSQ). Prior to working at CMS, she worked as a legislative assistant in the U.S. House of Representatives. She is an attorney, licensed in Maryland.

Anne E. Trontell, MD, MPH, *(May 2014–August 2014)* is the Senior Advisor on Pharmaceutical Outcomes and Risk Management in the Agency for Healthcare Research and Quality's (AHRQ) Center for Outcomes and Evidence, where she is the Program Director for the Centers for Education and Research on Therapeutics (CERTs) Program, a longstanding research network of seven centers working on individual and collaborative projects to optimize the use of drugs, devices, and biological products. She contributes to multiple Effective Health Care Program activities, the most recent and significant being her leadership of the $120 million CHOICE portfolio of large-scale, rapid-cycle pragmatic/prospective clinical studies in comparative effectiveness. Dr. Trontell represents AHRQ on the Clinical Trials Transformation Initiative, the Federal Working Group for the FDA mini-Sentinel Initiative, and the FDA Drug Safety Board. A pediatrician and epidemiologist, Dr. Trontell has expertise in FDA drug review, safety surveillance systems and assessments, risk communication, and risk management based on nine years of experience and leadership within FDA's Center for Drug Evaluation and Research. Prior to FDA, she was Chief Scientist at the Health Care Financing Administration (HCFA) Office of Research and Demonstrations, where she helped lead outcomes research and public campaigns to promote preventive services use by Medicare beneficiaries. Dr. Trontell was an Epidemic Intelligence Service Officer at the Centers for Disease Control and Prevention and ran a small contract research group doing environmental safety and health consulting prior to her medical and public health training at Boston's Children's Hospital, the University of Pennsylvania, and the Harvard School of Public Health. She serves as a Captain in the US Public Health Service Commissioned Corps.

Carol J. Walton is the Chief Executive Officer of The Parkinson Alliance, a nonprofit organization dedicated to raising awareness and funds for Parkinson's disease research. The Parkinson Alliance is the umbrella organization responsible for the Parkinson's Unity Walk—the largest single-day grassroots awareness and fundraising event for the Parkinson's community that takes place each spring in New York City's Central Park.

She has been deeply involved in the Parkinson's community for many years. Her father was diagnosed with Parkinson's disease in the early 1980s, at a time when it was extremely difficult to find information on this disease. She decided to devote her time, talent, and energy to help bring Parkinson's into the spotlight. From 1994 to 1999, she was with the National Association for the Self-employed (NASE), where she sold health and life insurance during nights and on weekends, enabling her to do volunteer work for Parkinson's during the day. In 1994, she attended a Parkinson's Action Network Public Policy Forum in Washington, DC, and volunteered as an advocate for research. She spent a great deal of time on Capitol Hill, meeting with members of Congress—and her efforts helped to get the Morris K. Udall Parkinson's Research Act passed in 1997. During that forum, she met Margaret and Martin Tuchman who were also advocates. They shared her vision and offered her the opportunity to create a new foundation, known today as The Parkinson Alliance. She is a Board Member of The Parkinson Alliance, PAN, and the Parkinson's Unity Walk.

Natalia Wilson, MD, MPH, is Associate Director in the School for the Science of Health Care Delivery and Academic Program Director for Medical Studies in the College of Health Solutions at Arizona State University. Prior to this role she was Co-director of the Health Sector Supply Chain Research Consortium in the WP Carey School of Business at ASU. Dr. Wilson practiced in a community-based internal medicine practice where she focused on preventive medicine and women's health. Areas of research focus include unique device identification and trust in health care. Dr. Wilson received her undergraduate degree in chemistry from Cornell University, medical degree from Georgetown University and trained in internal medicine at Vanderbilt. She additionally earned a Master of Public Health degree from the University of Arizona. She was a member of the Brookings Institution Unique Device Identification Workgroup and contributor to *Unique Device Identifiers (UDI): A Roadmap for Effective Implementation*.

II. Selection Criteria of the Members of the National Medical Device Postmarket Surveillance System Planning Board

The Planning Board is a multi-stakeholder group, representing a diverse set of relevant perspectives and expertise that promoted and brought the voice of their respective stakeholder groups, and ensured transparency. The Board was formed to engage content experts to develop a long-term vision of a National Medical Device Postmarket Surveillance System. The Engelberg Center for Health Care Reform at Brookings supported the Planning Board's work which was conducted through a series of meeting and regular conference calls over the course of nine months. The Planning Board members are volunteers and did not receive compensation for their service. Brookings issued a public call for nominations and an independent committee selected the Planning Board membership. More information about the Planning Board, including selection criteria and the nomination process, can be found on the Engelberg Center's website.

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