National Evaluation System for health Technology

The FDA is building the foundation for a National Evaluation System for health Technology (NEST) to more efficiently generate better evidence for medical device evaluation and regulatory decision-making. A national evaluation system would generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence, and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.

The collaborative national evaluation system will link and synthesize data from different sources across the medical device landscape, including clinical registries, electronic health records and medical billing claims. A national evaluation system will help improve the quality of real-world evidence that health care providers and patients can use to make better informed treatment decisions and strike the right balance between assuring safety and fostering device innovation and patient access.

History of National Evaluation System

A national evaluation system evolved out of a vision for a medical device postmarket surveillance system described in two FDA white papers. The initial report, "Strengthening Our National System for Medical Device Postmarket Surveillance," was issued in 2012 and provides an overview of FDA's medical device postmarket authorities and the current U.S. medical device postmarket surveillance system. The update to the report, issued in 2013, details the concrete steps that will promote more efficient collection of better and timelier data, helping to identify issues more quickly. Subsequently, FDA issued two 5-year program announcements (PAR-13-202 and PAR-13-232) requesting proposals from prospective partners to build the scientific infrastructure and methodology necessary to further develop and implement these plans through cooperative agreements.

Under a cooperative agreement with FDA, the Brookings Institution convened a multi-stakeholder planning board as described in the 2013 update. In February of 2015, the planning board issued its first report titled, "Strengthening Patient Care: Building a

National Postmarket Medical Device Surveillance System" which sets out the key steps towards developing a national system to generate real-world evidence on device performance, while supporting improvements in patient safety and health outcomes. This report first introduces the concept of an independent, transparent coordinating center to support the system's development and implementation.

The system was renamed an "evaluation system" to reflect the broad evidence needs of stakeholders with the August 2015 release of the report "Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research". MDEpiNet, a broad-based public-private partnership initially envisioned and launched by FDA in 2010, produced this report and is working to build infrastructure, and develop tools and methods for the national system.

In January 2016, the FDA cooperative agreement held by the Brookings Institution was transferred to the Duke-Robert J. Margolis, MD, Center for Health Policy (Duke-Margolis). In April 2016, Duke-Margolis published the second planning board report, "Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System." This document further clarifies the expectations, roles, and responsibilities of the coordinating center described in the 2015 planning board report. This additional detail provides insight into the coordinating center's expected business practices. In September 2016, Duke-Margolis Center for Health Policy published "The National Evaluation System for health Technology: Priorities for Effective Early Implementation", the third in a series of planning board reports. This report provides specific governance and oversight recommendations for the coordinating center, as well as identifies priority areas and projects to support medical device evaluation and surveillance.

FDA Activities

Establishing a national evaluation system for health technology is one of CDRH's 2016-2017 strategic priorities. The FDA is committed to building this system with our partners to generate real-world evidence on device performance by undertaking a number of activities, including:

- Awarding grants received through PAR-13-202 and PAR-13-232 to support NEST development and implementation;
- Issuing draft guidance to clarify how real-world evidence may be used to support pre- and postmarket regulatory decisions;
- Increasing access to and use of real-world evidence to support regulatory decisions;
- Working with the medical device ecosystem e.g. federal partners, health care system, manufacturers, payers and patients to build NEST.

Additional Resources

- The National Evaluation System for health Technology: Priorities for Effective Early Implementation - September 2016
- Need for a National Evaluation System for Health Technology. The Journal of the American Medical Association (JAMA). July 11, 2016.
- Better Evidence on Medical Devices: A Coordinating Center for a 21st Century National Medical Device Evaluation System – April 2016
- CDRH 2016-2017 Strategic Priorities (PDF - 249KB)
- Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research - August 2015 (PDF - 2.3MB)
- Strengthening Patient Care: Building a National Postmarket Medical Device Surveillance System - February 2015 (PDF - 1.2MB)
- Advancing Medical Device Postmarket Surveillance Infrastructure and Epidemiologic Methodologies through Multi-stakeholder Partnership (U01)
- Enhancing post-market surveillance through developing registries for medical device epidemiology (U01)
- Strengthening Our National System for Medical Device Postmarket Surveillance: Update and Next Steps - April 2013 (PDF - 289KB)
- Strengthening Our National System for Medical Device Postmarket Surveillance - September 2012 (PDF - 403KB)
- Unique Device Identification. FDA Website.

More in CDRH Reports

CDRH Preliminary Internal Evaluations

CDRH Plan of Action for 510(k) and Science

FDASIA Health IT Report

Medical Device Reporting (MDR) Rate in 510(k) Cleared Devices Using Multiple Predicates

National Evaluation System for health Technology

Regulatory Science Report

Reports to Congress

Understanding Barriers to Medical Device Quality

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