

# National Evaluation System for health Technology Coordinating Center

Responsible sharing and efficient analysis of real-world evidence to inform and empower patients, accelerate medical device innovation, and improve health care outcomes

Stakeholders across the medical device ecosystem stand to benefit from improved use of real-world evidence (RWE) generated in the routine course of care. Opportunities include increased patient awareness of device safety issues, low-cost efficient evidence generation for regulatory review, and generation of clinical research evidence from routine clinical care. The medical device National Evaluation System for health Technology (NEST) seeks to establish foundational principles of trust, transparency, scalability, sustainability, and accountability in order to identify opportunities for mutual benefit across diverse stakeholders and often competing priorities. A Planning Board convened by the Duke-Margolis Center for Health Policy in late 2015 envisioned NEST as a voluntary network of data partners able to efficiently consolidate RWE to inform medical device evaluation and support regulatory decision-making throughout the total product lifecycle (TPLC).

In September 2016, FDA awarded a grant for the NEST Coordinating Center (NESTcc) to the Medical Device Innovation Consortium (MDIC). MDIC is a 501(c)(3) public-private partnership created with the objective of advancing regulatory science of medical devices for patient benefit. MDIC is responsible for establishing NESTcc by 1) engaging stakeholders, 2) establishing organizational governance, 3) developing shared resources to facilitate stakeholder alignment and collaboration, and 4) achieving organizational sustainability.

NESTcc will have broad representation from across the ecosystem on the Coordinating Center's Governance Committee. With support from the Coordinating Center's Executive Director and staff, the Governance Committee will recruit Expert Advisory Working Groups, develop NESTcc bylaws, and undertake the development of shared resources through specific demonstration projects. Leveraging strategies such as data-sharing agreements and pre-competitive frameworks for technological innovation, these demonstration projects will support NESTcc in proposing strategies that best address potentially competing stakeholder priorities.

NESTcc's organizational goal is to apply an inclusive, patient-centered approach to increase the responsible use of RWE across the TPLC for a diverse set of stakeholders in a cost-effective and sustainable manner by pursuing the following activities:

- **Governance Committee:** Establish a governance committee of key stakeholders committed to the success of NEST and charged with inaugurating a Coordinating Center that is inclusive, patient-focused, and anchored in accountability and transparency
- **Organizational Design:** Define a decentralized strategy for responsible data sharing and analysis, a privacy-preserving structure for efficient collection and dissemination of data between different stakeholder constituencies, and a system of standards to facilitate data reporting and auditing in a decentralized and federated environment
- **Competitive Innovation:** Drive innovations in the accessibility and analysis of data that preserves patient privacy by allowing 3rd party data warehouses and/or data integrators to compete for NESTcc business flow infrastructure
- **Demonstration Projects:** Conduct demonstration projects to develop, verify, and operationalize methods of evidence generation and data sharing, demonstrate scalability across different stakeholders and device types, and identify strategies for NESTcc's sustainability

