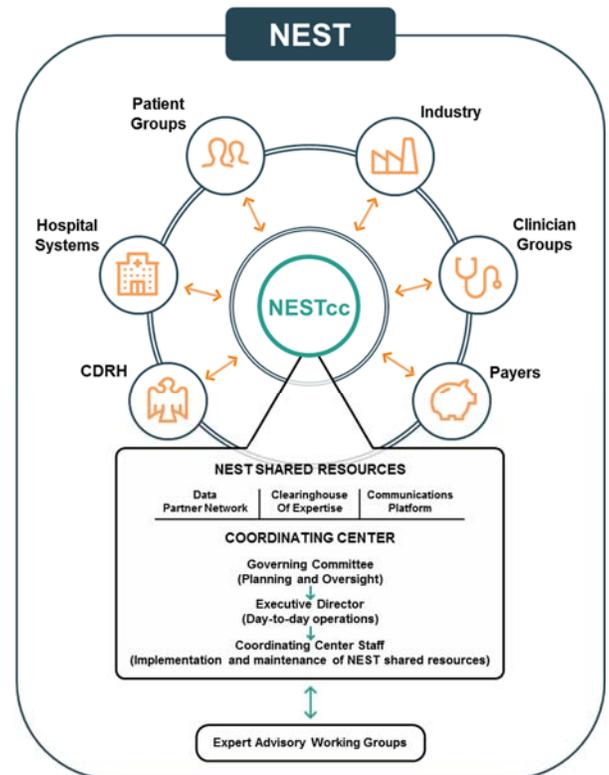


# National Evaluation System for health Technology Coordinating Center

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 improved patient and provider ability to make care decisions based on robust data. 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 Governing Committee. With support from the Coordinating Center's Executive Director and staff, the Governing 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:** Establish a functional governance structure comprised of an Executive Director, Governing Committee, and Work Groups; governance bodies will be comprised 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
- **Demonstration Projects:** Recognize 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
- **Key Functions and Sustainability:** Develop NESTcc functions that align to NEST's mission to improve and expand the use of RWE and that fit into a sustainable business model
- **Communication and Education:** Undertake outreach and education activities to engage stakeholders from across the medical device ecosystem, raise awareness of forthcoming demonstration projects, and support the long-term sustainability of the Coordinating Center