



NEST

National Evaluation System
for health Technology
Coordinating Center

THE CHALLENGE

An adequate infrastructure to enable access to, collection of, and use of real-world evidence (RWE), such as evidence collected during clinical care, is limited. The inability to access and integrate longitudinal datasets has slowed medical device innovation, delayed the detection of safety signals, and created regulatory inefficiencies. Solving these challenges could improve patients' timely access to safe medical devices and their quality of life.

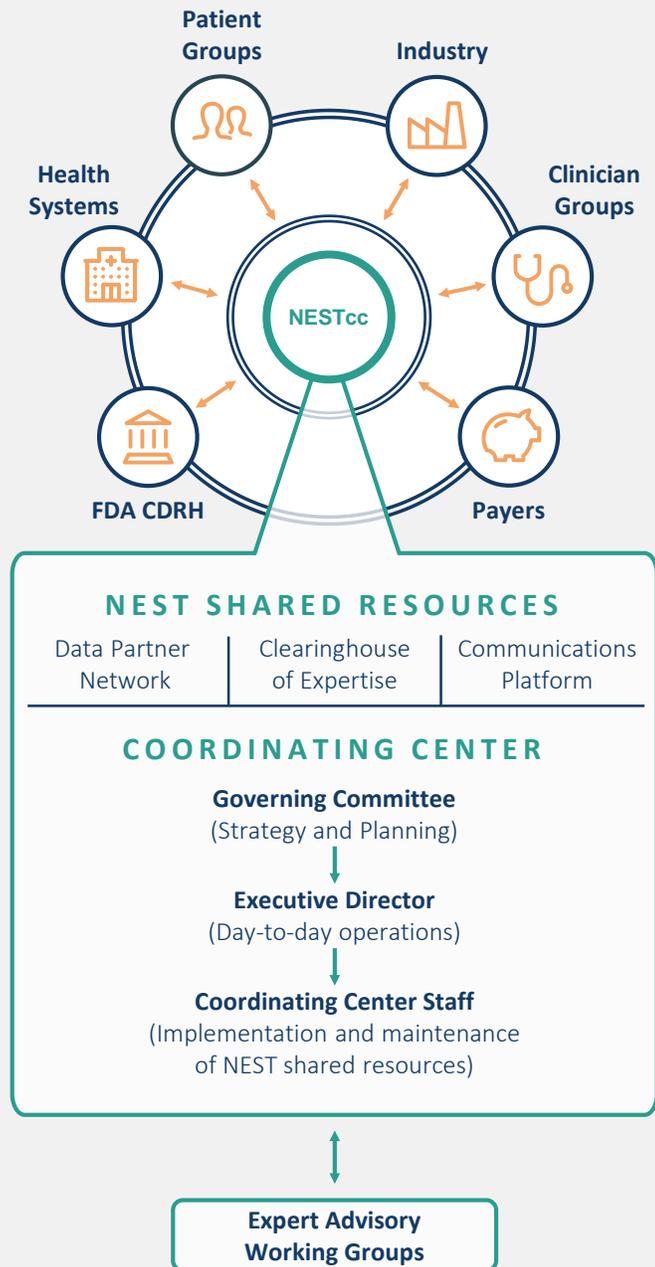
THE SOLUTION

In September 2016, FDA awarded a grant to the Medical Device Innovation Consortium (MDIC) to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). The selection of a third-party entity was important given the need for NESTcc to establish relationships and agreements between partners in a neutral, objective manner, and to solicit a balanced representation from stakeholders.

NESTcc's mission is to catalyze the timely, reliable, and cost-effective development of RWE to enhance regulatory and clinical decision-making within the medical device ecosystem—including imaging and diagnostics—in order to improve patient outcomes.

BENEFITS TO THE MEDICAL DEVICE ECOSYSTEM

Real world evidence (RWE) generated in the routine course of care, or at home, can benefit all members in the NEST ecosystem, informing and empowering patients, accelerating medical device innovation, and improving health care outcomes.



ACTIVITIES UNDERWAY

The NESTcc has completed the following start-up activities since its award in September 2016:



MDIC's Board of Directors has established the inaugural NESTcc **Governing Committee** including patient, clinician, medical device industry, regulatory, health system, and payer stakeholders



NESTcc has posted a **Request for Information (RFI)** seeking third-party data and analytics solutions to collect, link, and analyze medical device data for RWE generation



NESTcc is currently soliciting and reviewing **Demonstration Projects** that provide scalable methods for RWE use by stakeholders across the healthcare ecosystem



NESTcc is forming a **Data Partner Network** to generate concepts, partnership agreements, and potential pilot ideas to enable future data sharing and ecosystem collaboration

In the coming months, NESTcc will **finalize selections of demonstration projects, continue to develop its Data Partner Network** and **develop a sustainability model** for the organization to continue beyond its initial 5-year seed funding.

STAKEHOLDER ENGAGEMENT

NESTcc will work across stakeholder groups to communicate the value of RWE

NESTcc will engage all stakeholder groups to identify demonstration projects and other solutions for RWE's application for medical devices, imaging and diagnostics

NESTcc will incorporate the patient perspective into its design, programs, and initiatives



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