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National Evaluation System for health Technology Coordinating Center (NESTcc) Selects

Medical Device Real-World Evidence Demonstration Projects

Projects support NESTcc's mission to establish functional and efficient pathways for medical device evidence generation

Arlington, VA - (January 29, 2018) - The [National Evaluation System for health Technology Coordinating Center](#) (NESTcc) has selected eleven [demonstration projects](#) for their potential to provide proof of concept for innovative and scalable approaches to real-world evidence (RWE) generation across the medical device total product life cycle (TPLC). This group of demonstration projects explores diverse aspects of evidence generation methods and data use that have the potential to demonstrate scalability across healthcare systems, device types, and manufacturers.

"Through the demonstration project designation, NESTcc is engaging with national experts and leaders in the real-world evidence field from industry, academia, and the FDA, and leveraging the lessons from their pioneering work to support NESTcc's launch. Not only will these projects shed light on challenges and lessons learned in the design and execution of real-world evidence studies, but they will also identify gaps where NESTcc can help accelerate the use of medical device real-world evidence to support regulatory, coverage, patient, and clinical decision-making," said Rachael L. Fleurence, PhD, Executive Director of NESTcc. *"The lessons from the NESTcc demonstration projects will be critical in informing the Coordinating Center's strategy as it establishes the NESTcc Data Network focused on medical devices, an activity which is already underway and expected to make significant headway throughout 2018.*

The projects, already underway at participating organizations and expected to be completed by the end of 2018, employ a range of health technologies — including traditional medical devices, imaging technologies, and In Vitro Diagnostics — across pre-market, label expansion, post-market, and surveillance use-cases. Real-world data sources include different combinations of administrative claims, electronic health records, and patient and device generated data, that will be linked when necessary to provide data suitable for generating robust evidence.

Projects mainly focused on Pre-Market requirements:

- Lung-RADS Assist: Artificial Intelligence Model Verification, Reporting, and Monitoring
- Registry Assessment of Peripheral Interventional Devices (RAPID) - Superficial femoral and Popliteal Evidence Development (SPEED) as first device evaluation project
- SAFE STEMI for Seniors: An International CRN-based Prospective Randomized IDE Study of Labelling for Diagnostic and Therapeutic Devices Used in Seniors Suffering Heart Attack

Projects mainly focused on Post-Market requirements (including Post-Approval Studies)

- Developing and Implementing Sustainable Real-World Evidence Infrastructure for in vitro Diagnostics (IVDs) Through Systemic Harmonization and Interoperability for Enhancement of Laboratory Data (SHIELD)
- Electrophysiology Predictable and Sustainable Implementation of National Registries (EP PASSION)
- Feasibility Study to Evaluate the use of mHealth as Data Source in Post-Market Surveillance
- Post-Market Medical Device Surveillance with a Novel mHealth Platform
- Use of EHR-Based Data Network to Support Evidence Generation Across the Total Product Life Cycle (TPLC)
- Use of linked implantable device/Medicare data to assess association between device diagnostics and patient outcomes

Projects mainly focused on Surveillance:

- ICD Registry DELTA Active Surveillance Pilot Study
- Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

For more information about NESTcc Demonstration Projects including descriptions and participating organizations, please visit: <https://nestcc.org/demonstration-projects/>

About the National Evaluation System for health Technology Coordinating Center

In 2016, the U.S. Food and Drug Administration (FDA) awarded the Medical Device Innovation Consortium (MDIC) \$3 million in seed funding to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). The Coordinating Center seeks to support the sustainable generation and use of timely, reliable, and cost-effective Real-World Evidence (RWE) throughout the medical device lifecycle, using Real-World Data (RWD) that meets robust methodological standards and is generated in the course of clinical care and everyday life by patients, providers, or payers, and for the purpose of enhancing regulatory and clinical decision-making. For more information, visit <http://www.nestcc.org>.

About the Medical Device Innovation Consortium

Founded in 2012, the Medical Device Innovation Consortium (MDIC) is the first public-private partnership created with the sole objective of advancing medical device regulatory science throughout the total product life cycle. MDIC's mission is to promote public health through science and technology and to enhance trust and confidence among stakeholders. MDIC works in the pre-competitive space to facilitate development of methods, tools, and approaches that enhance understanding and improve evaluation of product safety, quality, and effectiveness. Its initiatives improve product safety and patient access to cutting-edge medical technology while reducing cost and time to market. For more information, visit <http://www.mdic.org>.

Funding for NESTcc was made possible, in part, by the Food and Drug Administration through grant (1 U01 FD 006292-01). Views expressed in written materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services; nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.

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