MEDICAL DEVICE INNOVATION CONSORTIUM

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For Immediate Release

Medical Device Innovation Consortium (MDIC) Awarded $3 million for National Evaluation System for health Technology Coordinating Center

MINNEAPOLIS, Minn. – (September 13, 2016) – The U.S. Food and Drug Administration (FDA) has awarded the Medical Device Innovation Consortium (MDIC) $3 million in seed funding to establish the Coordinating Center for the Medical Device National Evaluation System for health Technology (NEST).

This award will operationalize the Coordinating Center for NEST. The initial phase will include demonstration projects piloting methods for tracking medical device data and patient-reported outcomes through the use of real-world evidence. This use of real-world evidence to support product approvals/clearances of public health importance has the potential to shift premarket data collection to the postmarket setting and to meet postmarket data collection commitments through a modern system that leverages electronic health information generated in the clinical and home setting.

“We are thrilled that MDIC has been selected to lead this important effort,” said MDIC Board Chairman Mike Minogue, President, CEO and Chairman of Abiomed. “There is great potential in using real-world data to foster innovations in medical device technology that will lead to optimized outcomes for patients and improved quality of life. In addition, real-world evidence will help measure the cost-effectiveness of these new technologies. MDIC is uniquely suited to provide the leadership and governance structure necessary to bring diverse stakeholders together to lead a Coordinating Center for NEST that meets the needs of patients, regulators, and industry.”

“Building a strong coordinating center for the National Evaluation System for health Technology is critical to making this system a reality,” said Jeffrey Shuren, M.D., director of the FDA’s

Center for Devices and Radiological Health. “The FDA looks forward to collaborating with the consortium in building NEST with the goal of linking and synthesizing data across the medical device landscape, including clinical registries, electronic health records, and medical billing claims.”

NEST 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.

MDIC Board member Richard Kuntz, “As Chief Scientific, Clinical and Regulatory Officer at Medtronic, I support MDIC’s objective to operate a decentralized Coordinating Center in order to engage the best experts and other stakeholders to improve the rigor of post-market medical device evaluation and to assure the best program possible to measure safety and effectiveness for medical devices in the US that is transparent and patient-centered.”

MDIC President and CEO Bill Murray, “We are honored to take on this important role in shaping the future of the medical devices industry. MDIC’s public-private partnership and focus on regulatory science will assure that all stakeholders will have a voice in the development of a robust Coordinating Center for the Medical Device National Evaluation System for health Technology that has the potential to increase efficiency and accelerate patient access to life-saving medical technology.”

With the addition of the Coordinating Center to MDIC’s roster of activities, MDIC will be moving its executive headquarters to the Washington, DC area in late 2016. MDIC will continue to house project management and operational activities at the existing office in Minneapolis, MN.

Murray, Minogue and Shuren will present at MDIC’s Annual Public Forum on September 21 in Washington, DC, where they will discuss the future vision for the Coordinating Center (http://mdic.org/2016-annual-public-forum/).

About 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. We work 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. Our initiatives improve product safety and patient access to cutting-edge medical technology while reducing cost and time to market. For more information, visit www.mdic.org.

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