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Medical Device Innovation Consortium Announces Rachael L. Fleurence, Ph.D. Appointed as Executive Director of the National Evaluation System for health Technology Coordinating Center (NESTcc)

Arlington, VA - (April 11, 2017) - The Medical Device Innovation Consortium (MDIC) has announced Rachael L. Fleurence, Ph.D. has been selected to serve as the National Evaluation System for health Technology (NEST) Coordinating Center's first Executive Director effective April 24, 2017. She joins MDIC from the Patient-Centered Outcomes Research Institute (PCORI) where she has led PCORI's initiative to build the National Patient-Centered Clinical Research Network, or PCORnet, for the past five years. PCORnet has been a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United-States.

In September 2016, MDIC was awarded \$3M in seed funding by FDA to establish the NEST Coordinating Center. The goal of NEST is to more efficiently generate better evidence for medical device evaluation and regulatory decision-making. A national evaluation system would generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence, and applying advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices. The initial phase of the project has been focused on hiring the executive director and establishing coordinating center governance.

"We are thrilled to have Dr. Fleurence lead the Coordinating Center," said MDIC Board Chairman Mike Minogue, President, CEO and Chairman of Abiomed. "The first step in building a strong organization is hiring the right leadership. Rachael is an established leader with direct experience in building a national data network."

In accepting the position as Executive Director, Dr. Fleurence said, "I am thrilled to lead this exciting initiative between stakeholders across the medical technology ecosystem under the auspices of the MDIC. With its key objectives of ensuring safety, expediting patient access, and enabling innovation, I believe that NEST has the potential to truly transform the medical device ecosystem over the next few years."

"Bringing on a leader with experience building patient-centered data networks is critical to the success of the Coordinating Center," said Jeffrey Shuren, M.D., J.D. director of the FDA's Center for Devices and Radiological Health. "We look forward to collaborating with Dr. Fleurence to build a sustainable Coordinating Center for NEST."

"We have greatly appreciated Rachael's energetic leadership as she guided PCORnet to stability and achievement," said Dr. Joe Selby, PCORI Executive Director. "We'll miss her immensely, but NEST is a perfect next step and she's the ideal choice to further the vision we share of harnessing clinical data and stakeholder input in service of the research needs of patients, clinicians, policymakers, and manufacturers."

“I have had the privilege of observing Rachael’s leadership firsthand in her role on the MDIC Board of Directors,” said Bill Murray, President and CEO of MDIC. “With her hiring, we have taken a major step in ensuring the success of the Coordinating Center.”

The initial focus of Dr. Fleurence will be to establish the Coordinating Center governance structure and identifying demonstration projects that pilot methods for tracking medical device data and patient-reported outcomes through the use of real-world evidence.

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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