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For Immediate Release

National Evaluation System for health Technology Coordinating Center (NESTcc) selects inaugural Governing Committee

Arlington, VA – (July 13, 2017) – The Medical Device Innovation Consortium (MDIC) Board of Directors has established the inaugural Governing Committee for the National Evaluation System for health Technology Coordinating Center (NESTcc). The Governing Committee will recommend the strategic direction for NEST. Its members represent NEST's diverse stakeholders, including patients, clinicians, medical device industry, regulators, health systems, and payers. The Committee's first priority is to select NEST demonstration projects that pilot the use of real-world evidence (RWE) to support regulatory decision-making at different stages of the medical device total product life cycle.

The inaugural NESTcc Governing Committee members are:

- **Naomi Aronson, PhD** – Executive Director of Clinical Evaluation, Innovation, and Policy at the Blue Cross Blue Shield Association
- **Kathleen Blake, MD, MPH** – Vice President of Healthcare Quality at the American Medical Association (AMA)
- **Marc Boutin, JD** – CEO of the National Health Council (NHC)
- **Mark Deem** – Managing Partner at The Foundry, LLC, Venture Partner at Lightstone Ventures, and Medical Device Manufacturers Association (MDMA) nominee
- **Bill Hanlon, PhD** – Chief Development Officer and Head of Global Regulatory Affairs at LabCorp/Covance, and American Clinical Laboratory Association (ACLA) nominee
- **Adrian Hernandez, MD, MHS** – Professor of Medicine at Duke School of Medicine, Director of research, quality, and outcomes at Duke Heart, and Director of Health Services and Outcomes Research at the Duke Clinical Research Institute (DCRI)

- **Tamara Syrek Jensen, JD** – Director of Coverage and Analysis Group at the Center for Clinical Standards and Quality at the Centers for Medicare and Medicaid Services (CMS)
- **Harlan M. Krumholz, MD, SM** – Harold H. Hines, Jr. Professor of Medicine and Epidemiology & Public Health at Yale University, and Director of the Yale New Haven Hospital Center for Outcomes Research and Evaluation (CORE)
- **Elizabeth McGlynn, PhD** – Vice President of Kaiser Permanente Research, and Executive Director of the Kaiser Permanente Center for Effectiveness & Safety Research
- **Michelle McMurry-Heath, MD, PhD** – WW Vice President Regulatory and Clinical Affairs at Johnson & Johnson Medical Device Companies, and Advanced Medical Technology Association (AdvaMed) nominee
- **Vance Moore** – President of Business Integration at Mercy
- **William Murray** – President and CEO of the Medical Device Innovation Consortium (MDIC)
- **Jeffrey Shuren, MD, JD** – Director of FDA's Center for Devices and Radiological Health (CDRH)
- **Sharon Terry** – President and CEO of Genetic Alliance
- **Diane Wurzburger, JD** – Regulatory Affairs Executive at GE Healthcare, and Medical Imaging & Technology Alliance (MITA) nominee

NESTcc supports the operations of NEST, a national network designed to efficiently generate better evidence for medical device evaluation and regulatory decision-making. NEST will be a patient-focused, strategically-driven, coordinated network of voluntary RWE partnerships. Together, institutional data partners, methods partners, and patient communities will coordinate efforts to generate higher quality data at lower costs to inform and improve patient care.

Dr. McMurry-Heath, World Wide Vice President of Regulatory and Clinical Affairs at Johnson & Johnson Medical Device Companies and AdvaMed nominee to the NESTcc Governing Committee stated, "NEST represents a groundbreaking opportunity to effectively and efficiently capture medical device clinical experience in the real world, and I'm delighted and honored to be a part of the process."

Governing Committee members were selected through an open call for nominations published in December 2016, followed by a rigorous review process that included a diverse set of reviewers from the medical device industry, academia, and regulatory agencies.

Commenting on the Governing Committee selection process, NESTcc Executive Director Rachael Fleurence, Ph.D. said, “members were selected based on their ability to represent broad stakeholder groups and provide the leadership and vision required to realize the opportunities and benefits NEST can deliver to the ecosystem.” Referencing NESTcc’s commitment to transparency, she encouraged stakeholders to visit her blog (mdic.org/cc/blog) to learn more about the selection process.

Dr. Fleurence also highlighted the membership of National Health Council CEO Marc Boutin and Genetic Alliance President and CEO Sharon Terry – leaders of organizations that together represent more than 130 million American patients. CDRH Director Jeffrey Shuren, M.D., J.D., said he is “pleased to serve on the governing committee to help NEST achieve its potential and to advance FDA’s mission for patients: first-in-the-world access to innovative and safe medical devices.”

Echoing the sentiments of other Committee members, Dr. Harlan Krumholz said that NEST has “the potential to ensure that we are continuously learning about the safety and effectiveness of medical devices after they are approved and integrated into practice. The alignment of government, industry, patient groups, and academia is truly remarkable – and the commitment to transparency, accountability, and progress is laudable – with the pieces in place, the time is now to make things happen and show what is possible in a public-private partnership focused on the common good.”

About 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 Coordinating Center for the Medical Device National Evaluation System for health Technology (NEST). The Coordinating Center’s mission is to support the sustainable generation and use of real world evidence throughout the medical device lifecycle, using real world data that meets robust methodological standards and is generated in the course of clinical care by patients, providers, or payers, and

for the purpose of enhancing regulatory and clinical decision-making. For more information, visit www.nestcc.org.

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. 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 www.mdic.org.

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