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Contact:  
Stephanie Christopher  
Program Manager  
schristopher@mdic.org  
952-314-2730

For Immediate Release

**Medical Device Innovation Consortium (MDIC) announces new collaboration to move clinical trials from generic p-values of 0.05 to therapy-specific patient-values**

**MINNEAPOLIS, Minn.** – (October 18, 2016) – The Medical Device Innovation Consortium (MDIC) is pleased to announce the start of a new research project intended to integrate patient preferences on benefits and risks into the statistical design of clinical trials. The pilot of this project is a collaboration of MDIC, The Michael J. Fox Foundation for Parkinson’s Research (MJFF), the US Food and Drug Administration (FDA), RTI Health Solutions, and the Massachusetts Institute of Technology (MIT).

This project will develop and test a method for incorporating patient preference information as an explicit means to set significance levels in clinical trial design. While the pilot focuses on a specific disease state, Parkinson’s disease, the method may be generalizable to other diseases and has the potential to remove barriers to therapy access by giving patients a pathway to breakthrough, lifesaving technologies based, in part, on their risk tolerance.

For chronic, debilitating and terminal illnesses with no effective therapies, the standard statistical threshold for determining therapeutic effectiveness in clinical trials may not reflect patients’ perspectives on the trade-off between the risk of approving an ineffective therapy (Type I statistical errors) and rejecting an effective therapy (Type II statistical errors).

Clinical trials designed with consideration of patient preference information may expedite trials and enable groups representing rare diseases or smaller patient populations to provide input so that trials are designed with a focus on the patient.

By designing clinical trials that reflect patients' urgency and risk tolerance, scarce resources can be allocated more efficiently, bringing more therapies to more patients faster and more cost-effectively.

This project marks the first time MDIC has partnered directly with a patient group to engage patients as research partners. Representatives from the MJFF Patient Council are serving in the Parkinson's disease pilot as patient scientists and will give direct input on the design and execution of the project. MDIC President and CEO Bill Murray said, "We view this project as potentially transformative in medical device clinical trials and we are thrilled to work with The Michael J. Fox Foundation, who are the recognized leaders in mobilizing Parkinson's patients to participate in clinical trials. We couldn't ask for a better patient partner."

Anne Cohn Donnelly, co-chair of the working group serving this project from the MJFF Patient Council, said, "People with a disease like Parkinson's can be more than research subjects; we can be partners in the design and focus of clinical trials. We welcome this opportunity to work with MDIC, the FDA and other partners to create a mechanism for the patient voice to be heard."

### **Media availability**

MDIC President and CEO Bill Murray will be available for media questions regarding this project and the recent announcement about the MDIC NEST Coordinating Center at the MDIC/AdvaMed/CDRH press conference on Wednesday, October 19, at 11:55 a.m. at the 2016 AdvaMed Conference at the Minneapolis Convention Center, room m101c.

### **Other MDIC News**

Last week, MDIC announced the release of its first report on comparative analysis of medical device quality (<http://mdic.org/wp-content/uploads/2013/05/Final.CaseforQualityAnalyticsRelease-20161011.pdf>.) The comparative analysis report is available at: <http://mdic.org/cfq/resource-center-for-sustained-quality/>.

### **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](http://www.mdic.org).

### **About The Michael J. Fox Foundation for Parkinson's Research**

As the world's largest nonprofit funder of Parkinson's research, The Michael J. Fox Foundation is dedicated to accelerating a cure for Parkinson's disease and improved therapies for those living with the condition today. The Foundation pursues its goals through an aggressively funded, highly targeted research program coupled with active global engagement of scientists, Parkinson's patients, business leaders, clinical trial participants, donors and volunteers. In addition to funding more than \$650 million in research to date, the Foundation has fundamentally altered the trajectory of progress toward a cure. Operating at the hub of worldwide Parkinson's research, the Foundation forges groundbreaking collaborations with industry leaders, academic scientists and government research funders; increases the flow of participants into Parkinson's disease clinical trials with its online tool, Fox Trial Finder; promotes Parkinson's awareness through high-profile advocacy, events and outreach; and coordinates the grassroots involvement of thousands of Team Fox members around the world.

For more information, visit us at [michaeljfox.org](http://michaeljfox.org), on [Facebook](#) or [Twitter](#).

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