The Food and Drug Administration's (FDA's)
2015 ORSI Science Symposium
April 27, 2015
SPEAKER ABSTRACTS AND BIOGRAPHIES

Session 4: Broad Agency Announcement (BAA) Research Contract Program Presentations – 1:45-3:00 PM

Speaker name and title	**Bill Murray, President and CEO of Medical Device Innovation Consortium (MDIC)**
Contractor	**Medical Device Innovation Consortium (MDIC)**
Biography	**Bill joined MDIC in August of 2013 as the first President and CEO. He has over 25 years of senior leadership experience spanning the range of privately financed start-up to billion dollar plus global businesses. Bill's small company experience spans 5 years as CEO and executive consultant, including 3 years as CEO of ReShape Medical. His large company experience includes leadership as the Molecular Biology Division President of Applied Biosystems, and at Medtronic where he spent nearly 20 years in various senior leadership positions, including President of the Pacemaker Business. Bill has also served as interim President and CEO of MTS Systems (MTSC) a public $SOOM industrial technology company. Bill currently serves on the Boards of MDIC, ILT, Sonex Health and Meso-Flow and previously served on the Boards of MTS Systems, LifeSync Holdings, and ReShape Medical. Bill has also served on various industry association and community leadership boards. He earned a Bachelor of Science Degree in Electrical Engineering from The University of Florida.**
Title of the project	**Patient-Centered Benefit/Risk Assessment : Developing a Useful Methodology for Integrating Patient-Centered Perspectives in Regulatory Decisions**
Presentation Abstract	**Patient Centered Benefit-Risk Project** **Since the 2012 CDRH Benefit-Risk Guidance recommended that sponsors interact with FDA staff regarding the development of patient centered risk-benefit information, there has been increased interest in understanding validated methods and tools for collecting patient preference information and how sponsors should collect and present that information to CDRH. As sponsors seek to include patient preference information as evidence in their regulatory submissions, there is a need to improve the understanding of how to collect and present validated patient centered benefit-risk information.** **A FDA Broad Agency Agreement (BAA) funded the development of a Patient Centered Benefit-Risk (PCBR) Framework developed by the Medical Device Innovation Consortium, a FDA-Industry public-private partnership, one of whose projects is to help investigators and regulators consider the patient perspective on the benefits and risks of medical devices. In order to properly take patient preferences into account, investigators and regulators must have reliable and accurate methods, tools, and approaches to capture and analyze the information to assure the level of evidence required for a regulatory decision. The Framework includes an evaluation of the potential value of patient preference information in regulatory benefit-risk decisions, factors to consider when incorporating patient preferences into regulatory submissions, a catalog of patient preference assessment methods and considerations for incorporating patient preference across the product lifecycle. The Framework is intended to serve as a tool to promote robust patient centered benefit-risk assessment in regulatory submissions.**