The one place where industry, non-profits & FDA can collaborate to make patient access to new medical device technologies faster, safer and more cost-effective

MassMEDIC Presentation

Bill Murray, President & CEO
Medical Device Innovation Consortium
The Medical Device Industry is Critical to Our Nation’s Health...

“Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world. The U.S. is the world’s leader in regulatory science, medical device innovation and manufacturing, and radiation-emitting product safety. U.S. post-market surveillance quickly identifies poorly performing devices, accurately characterizes real-world performance, and facilitates device approval or clearance. Devices are legally marketed in the U.S. and remain safe, effective, and of high-quality. Consumers, patients, their caregivers, and providers have access to understandable science-based information about medical devices and use this information to make health care decisions.”

Faster, Safer, More Cost-Effective
What is Regulatory Science?

- Provides the tools, standards, and approaches needed to evaluate the safety, effectiveness, performance, and quality of medical products
- Benefits patients by speeding the rate of important technologies reaching market
- Reduces time and resources needed for device development, assessment, and review. For example:
  - Can lead to quicker, more efficient device approvals
  - Can decrease the size and duration of pre-market clinical trials

Faster, Safer, More Cost-Effective
The Power of Collaboration

• The most effective way to advance medical device regulatory science is through collaboration.

• Regulatory science is big science. In the current fiscal climate, we need to pool people, resources, and ideas to drive breakthroughs.

• The Medical Device Innovation Consortium will promote these collaborations by establishing an independent non-profit that brings together industry, government, academia, and other stakeholders to this end.

• The MDIC will vastly expand our capacity for device-related regulatory science by creating a safe space for facile, creative, and ambitious medical device collaborations.
"This consortium is truly ground-breaking. It creates a safe space to collaborate on early-stage regulatory science efforts that will eventually benefit the entire industry: the advancement of innovation and ultimately, and most importantly, patients."

- FDA Commissioner Margaret Hamburg, MD

MPRNews, December 3, 2012

“What we've lacked is a structure like the Medical Device Innovation Consortium that allows for a larger number of parties to come together to develop these projects on an ongoing basis - a significantly more effective way to do research.”

- CDRH Center Director Jeffrey Shuren, MD, JD

MedPage Today, December 4, 2012
Challenges

• Limited federal government investment in regulatory science

• Private sector investments generally have been proprietary

• High cost of engaging in scientific collaborations due to administrative inefficiencies and legal issues

• Risk of legal liability when competitors collaborate

Opportunity: Establish a public-private partnership
MDIC Public-Private Partnership

Facilitate the development of tools, systems and approaches (Regulatory Science) to expedite access to innovative medical technology for patients

- OSEL/ODE/OIR/OSB are Fully Engaged on the Board, Committees & Working Groups
- NIH/Other Government Research Project Support

- Large & Small Company Representation
- Exclusively Medical Device
- Project Support

- Research alignment
- Education Support
- Research Project Support

FDA & other Government

Industry

Non-Profits
MDIC Value Proposition

- **For Regulators**: to develop a significant understanding of state of the art medical device regulatory science to support regulatory decision making
- **For Industry**: to increase the regulatory science knowledge base, informed with input from regulators, to influence development of industry standards and facilitate more cost effective and efficient development of new devices and diagnostics
- **For Academics**: to increase utilization of academic resources for training and research
- **For Patients**: to promote and support the development of safe and effective device therapies and enjoy first in the world access
- **For Providers**: to promote public health through effective collaboration and access to state of the art technology
The MDIC is a Public Private Partnership

There are many public-private partnerships in the healthcare space

- Medical Device Innovation, Safety and Security Consortium
- Biomarkers Consortium
- Critical Path Institute
- National Bone Health Alliance
- Observational Medical Outcome Partnership
- International Consortium for Innovation and Quality in Pharmaceutical Development

There are other public private partnerships focused on regulatory science

- Center of Excellence in Regulatory Science and Innovation (CERSI)-Georgetown
- CERSI-University of Maryland

The MDIC is uniquely focused on the medical device industry

- Preferentially focused on medical devices and regulatory science
- Industry led
- Close partnership with FDA
- National in scope
MDIC Scope and Activities

Medical Device Discovery and Development Path

- Basic Research
- Proof of Concept or Invention
- Precompetitive Space
  - Standards, data, and processes that are common across an industry
- Early-stage Technology Development
- Product Development
- Production and Marketing

- NSF, NIH Corporate Research, SBIR Phase I
- Angel Investors, Corporations, Technology Labs, SBIR Phase II
- Venture Capital
- Corporate Venture Funds, Equity, Commercial Debt

- Competitive Space
  - Data, processes, and know-how specific to a product

Regulatory science develops tools, methods, and standards to aid in this step

Reduce time and cost of device development and review

Resources
- People
- Intellectual Capital

Key
- Source frequently funds this technological stage
- Source occasionally funds this technological stage
MDIC History

Memorandum of Understanding (MOU) submitted December 2011

Business plan created October 2012

MDIC website launched Nov 12 2012

Articles of Incorporation filed August 2012

MDIC Nation wide rollout Washington, D.C. December 2012

MDIC at LSA Conference December 5 2012

Convene First meeting of the full Board. Approve Bylaws; approve Budget & administrative structure, confirm initial work priorities Feb 26, 2013

Convene Second meeting of the full Board. Gain approval of scoped projects May 28, 2013

Respond to Membership Requests December 2012

Convene Third meeting of the full Board. Review project structure & plans. Sept 12, 2013
MDIC Board & Membership
Board of Directors

Executive Committee

Allan Coukell | The Pew Charitable Trusts
Director of Drugs and Medical Devices
MDIC Vice-Chair

Vincent Forlenza | Becton, Dickinson and Company
President, CEO and Chairman
MDIC Finance Committee, Vice-Chair

William A. Hawkins III | Immucor, Inc.
President and CEO
MDIC Board Chair

Michael R. Minogue | Abiomed, Inc.
President, CEO and Chairman
MDIC Secretary; Membership Committee Chair

William V. Murray | MDIC
President & CEO
Medical Device Innovation Consortium CEO

David Perez | Terumo BCT
President and CEO
Chairman, Blood Management Business Division,
Terumo Corporation
MDIC Finance Committee Chair

Jeffrey Shuren, MD, JD | CDRH, FDA
Director, Center for Devices and
Radiological Health
Food and Drug Administration

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Director, Center for Devices and
Radiological Health

Full Board

Glenn L. Criser | Biomet, Inc.
Senior VP, Quality/Regulatory/Clinical Affairs

Bryan Luce, Ph.D. | PCORI
Chief Science Officer

Randall Schiestl | Boston Scientific Corporation
VP, Global Operations and Technology

Kathy Hudson, Ph.D. | NIH
Deputy Director for Science, Outreach, & Policy

Karen Licitra | Johnson & Johnson
Worldwide Chairman, Global Medical Solutions

Tamara Syrek Jensen, J.D. | CMS
Deputy Director, Coverage and Analysis Group

Ross Jaffe, M.D. | Versant Ventures
Managing Director

Daniel J. Moore | Cyberonics, Inc.
President & CEO

Nadim Yared | CVRx
President & CEO

Sr.VP and Chief Scientific, Clinical & Regulatory Officer

Michael Rousseau | St Jude Medical
Group President

Dale Wahlstrom | LifeScience Alley and
The BioBusiness Alliance of MN
President & CEO

Peter Saltonstall | NORD
President & CEO
Initial Projects

Patient Centered Benefit-Risk Assessment

**Goal: Develop a framework for incorporating patient preferences into B/R assessment**

**MDIC:**
- Board Champion | Ross Jaffe, MD
- Managing Director | Versant Ventures
- Director | National Venture Capital Association
- Program Manager | Stephanie Christopher

**FDA:**
- Primary Investigator | Randall Brockman, MD
- Chief Medical Officer | Office of Device Evaluation (ODE)

Clinical Trial Innovation & Reform

**Goal: Improve the function of the clinical trial process while increasing efficiency and utility through a Total Product Lifecycle (TPLC) framework**

**MDIC:**
- Board Champion | Rick Kuntz, MD
- Sr VP & Chief Scientific, Clinical & Regulatory Officer | Medtronic
- Program Manager | Stephanie Christopher

**FDA:**
- Primary Investigator | Bram Zuckerman, MD
- Supervisory Medical Officer | Office of Device Evaluation (ODE)

Computer Modeling & Simulation

**Goal: Increase confidence in safety and efficacy, reduce clinical trial size and accelerate device review through regulatory grade computer models & simulations**

**MDIC:**
- Board Champion | Randy Schiestl
- VP, Global Operations & Technology | Boston Scientific
- Sr Program Manager | Dawn Bardot, PhD

**FDA:**
- Primary Investigator | Kyle J. Myers, PhD
- Director, Division of Imaging & Applied Mathematics | Office of Science & Engineering Laboratories (OSEL)
This project utilizes the March 28, 2012 FDA Guidance Document: *Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Approvals and De Novo Classifications* to help guide efforts to incorporate enhanced risk management into product reviews.

**Project Goals**

- Steering Committee in place
- Initial deliverables
  - Catalog of existing methods for assessing patient B/R preferences
  - Draft framework for incorporating patient preferences into B/R assessment
  - Applying for external grant support
MDIC
Clinical Trial Innovation & Reform

This project aims to improve the safety of the products being introduced into the market by improving the function of the clinical trial process while increasing its efficiency and utility.

**Project Goals**

- Adoption of Large Simple Trial Methods
- Refocus from “pre-market – post-market” framework to Total Product Lifecycle (TPLC) framework
- Rigorous analysis over TPLC where market release is incidental and continuous product updates inform the target patients, providers and public
- Shift in surveillance methods from reliance on voluntary complaints and return product analysis to rigorous clinical research estimations of safety and signal detection, further supporting earlier product release
- Accelerating First Human Use in the US
MDIC
Computer Modeling & Simulation

Increasing Confidence in Safety and Efficacy through Regulatory Grade Computer Models & Simulations

Project Goals

• Advancing medical device innovation, and evaluating new and emerging technologies
• Developing state of the art preclinical methods for assessing device safety and performance
• Developing novel ways to use clinical data in evaluating medical devices – Big Data
Example Team Structure

Computer Modeling & Simulation Team

Program Manager works with CM&S Steering Committee, MDIC staff, and project leads to develop scope and manage project resources, timelines, and deliverables.

draft of initial projects

Working Group (MDIC members)

Human Heart
- Sub-team lead Team members

Peripheral vasculature
- Sub-team lead Team members

Skeletal System
- Sub-team lead Team members

Nervous System
- Sub-team lead Team members

Biomaterials
- Sub-team lead Team members

TBD
- Sub-team lead Team members

* = proposed team member

MDIC Staff

President & CEO: Bill Murray
Program Administrator: Cynthia McKee

Dawn Bardot, Ph.D.
Program Manager

Steering Committee

Board Champion: Randy Schiestl
Program Manager: Dawn Bardot
FDA: Kyle J. Myers, Ph.D.
Industry

Expert Panel

Academia and Individuals

Grant Review

Team Chair
Team Members

TBD

MDIC
Medical Device Innovation Consortium
Align • Achieve • Accelerate
Membership

Membership and participation in the MDIC is open to representatives of organizations that are substantially involved in medical and/or medical device research, development, treatment, or education; the promotion of public health; or who have expertise in regulatory science.

- Membership is offered at several levels based on organization type and, if applicable, annual revenue
- Membership has not been offered to academic groups
- Membership has not been offered to individuals
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