MDIC

Medical Device Innovation Consortium

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MDIC Newsletter

July 2013

MDIC Progress Update

The MDIC held its second Board of Directors Meeting on May 28, 2013. The framing documents for the initial three projects were approved as well as the process to select program managers and begin project team formation. Program managers have been selected for 2 of the 3 projects and the third will be announced shortly. They are beginning to assemble their teams and establish time lines and budgets for team deliverables. Finally, the process to select a permanent Executive Director is nearing completion and the individual filling this role will be announced very soon.

Approved Projects

- Advancing Regulatory Science: Computational Modeling and Simulation in Regulatory Approval
- Patient Centered Benefit/Risk Assessments: Developing a Useful Methodology for Integrating Patient Centered Perspectives into Regulatory Decisions
- Clinical Trial Innovation and Reform: Restoring U.S. Leadership in Clinical Excellence and MedTech Innovation

Membership News

- MDIC membership: Interest in project activity and the FDA/industry public private partnership has exceeded the Board of Directors initial expectations and is continuing to build. By the end of July membership was nearly double the initial 2013 year end goal.
- The MDIC offers a unique opportunity for people from industry, academia and the FDA to work together in a formal public private partnership to remove barriers facing our industry. It is important that membership include the broad spectrum of stakeholders in the industry. Please contact us to become a member... regardless of your company size or industry segment, your voice and participation is important.

Recent and Upcoming Events Featuring MDIC

1. Going Beyond Regulatory Approval and Getting Back to the Science , Minneapolis MN, November 20, 2013
2. Medical Devices & In Vitro Diagnostics, Boston MA, October 1, 2013
3. The Patient Preference Initiative: Incorporating Patient Preference Information into the Medical Device Regulatory Processes, Silver Spring MD, September 18-19 2013
4. Virtual Prototyping, Modeling & Simulation, Minneapolis MN, August 8 2013
5. FDA & Regulatory Science, Minnetonka MN, July 9, 2013
6. MD&M East Conference, Philadelphia PA, June 17-20, 2013
7. FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices, Silver Spring MD, June 11-12, 2013
8. Ximedica, Providence RI, May 21, 2013
9. Medical Plastics conference, Boston MA, May 15 2013

Advancing Regulatory Science: Computational Modeling and Simulation in Regulatory Approval

Charter: To reduce time and cost required to develop and approve medical innovation, while improving patient safety, through the consistent application of validated computational modeling and simulation in device development and regulation. To facilitate collaboration across industry, academia, and government toward the ongoing advancement of the application of computational modeling and simulation to the development and regulation of medical devices.

Board Champion

Randy Schiestl
Vice President,
Global Operations
and Technology,
Boston Scientific
Corporation

Randall (Randy) Schiestl, PMP is the Vice President of Global Operations and Technology, Engineering Services Group at Boston Scientific where he leads a team to deliver computational analysis, design, engineering, packaging & labeling, customer focus, knowledge management and lab & test services for the corporation. He has BSME, MBA and Executive MBA degrees from the University of Minnesota. Randy received the UMAA Alumni Service Award from the College of Science & Engineering in 2011.

"I am honored and excited to be a part of the MDIC. We have a tremendous opportunity to accelerate innovative products-to-market by advancing Modeling and Simulation in both device design and regulation. In the upcoming weeks we will be working to identify the initial M&S steering committee members. I am pleased to have Kyle Myers, Ph.D. as our FDA partner in this process. Send recommendations for Steering Committee or Content Expert team members to me at DBardot@MDIC.org."

– Dawn Bardot, Ph.D.

Program Manager

Dawn Bardot, Ph.D, brings fifteen years of experience and expertise in computational model validation and uncertainty quantification. She is passionate about the application of modeling and simulation to improve health care and lower the cost of bringing products to market. As a member of the American Society of Mechanical Engineers, she serves as vice-chair of the Verification and Validation in Computation Fluid Dynamics and Heat Transfer Committee and sub-group chair of the Committee on Verification and Validation in Computational Methods for Medical Devices.

Dawn has worked with startup companies, government organizations, and academia on computer simulations and validation including high intensity focused ultrasound, patient specific noninvasive FFR, and medical oxygen regeneration for space flight. She has tackled the challenge of big data and data curation; disseminated and promoted the first computational model V&V standard; created, hired, and lead modeling teams.

Dr. Bardot has a BS and MS in mechanical engineering from Kansas State University, a PhD in mechanical engineering from the University of Washington, was an Innovation Fellow at the University of Minnesota Medical Devices Center, and spent two summers as a Faculty Fellow at NASA Marshal Space Flight Center.

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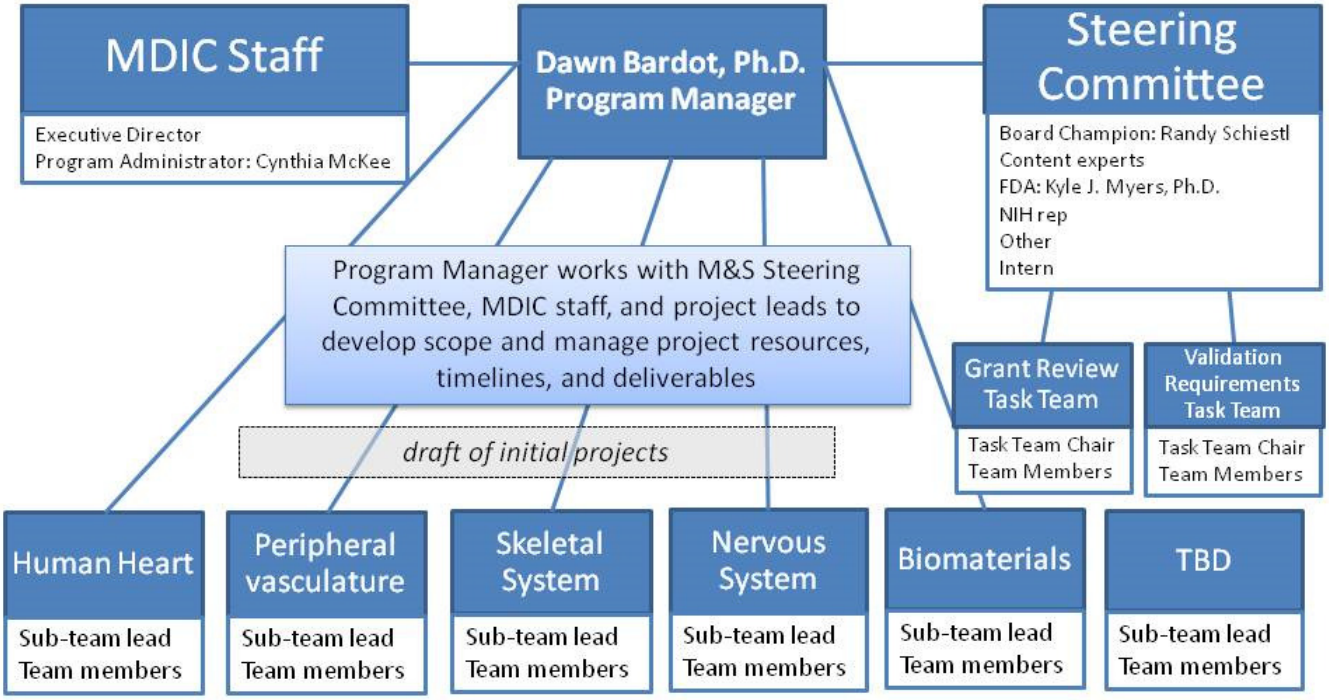
M&S Team Structure

Project: Computer Modeling & Simulation



MDIC Membership Committee Message

Michael Minogue, President, CEO & Chairman | Abiomed,
Chairman of MDIC Membership Committee

The successful outcome of the efforts of the MDIC is dependent on broad scale involvement by companies and professionals who are interested in helping patients receive safer, more advanced therapies at a lower cost and in less time. The projects the MDIC takes on will be in the pre-competitive space that will help the broadest selection of companies by sharing capabilities to address issues affecting products trying to enter the clinical environment. The leadership and involvement of individuals and organizations from the public, private and academic sectors are needed to make the benefits of this effort a reality.

Patient Centered Benefit/Risk Assessments: Developing a Useful Methodology for Integrating Patient Centered Perspectives into Regulatory Decisions

Charter: To establish a credible framework for defining patient preference regarding probable benefits and probable risks of a proposed medical device across a representative spectrum of conditions and patients who might be exposed to the device, and the application of this information to pre-market and post-market regulatory submissions and decisions.

Board Champion

Ross Jaffe, MD
Managing Director,
Versant Ventures
Director, National Venture
Capital Association (NVCA)

Dr. Ross Jaffe specializes in early-stage investing in medical devices, bringing significant clinical insight into each venture. Dr. Jaffe co-founded Versant Ventures in 1999 after spending nine years at Brentwood Venture Capital where, as a general partner, he led investments in medical devices, drug delivery, and healthcare information systems companies.

Dr. Jaffe completed his residency training in Internal Medicine/Primary Care at the University of California, San Francisco. Before and during medical school he was an Analyst for Lewin and Associates, as healthcare consulting firm, and a Research Associates at Dartmouth Medical School.

> "Developing a specific framework for defining patient preferences regarding the value of the probable benefits and the impact of potential risk of a medical device will help both the FDA and industry to keep pace with the needs of patients and help advance medical innovation."
>
> – Kelly Campbell Slone

Program Manager

Kelly Campbell Slone
Vice President, Federal
Life Science Policy, NVCA

Kelly Slone joined the National Venture Capital Association (NVCA) in April 2005 in a newly created position focused on representing NVCA's life sciences members on federal public policy issues. NVCA is the national trade association for the venture capital industry whose mission is to foster the understanding of the importance of venture capital to the vitality of the U.S. and global economies. Kelly is responsible for raising the visibility of NVCA's life science members to congressional, administrative, and regulatory leaders on the important role venture capital plays in the creation and development of disruptive medical therapies and technologies. She is also leads efforts to raise awareness on public policy issues that primarily impact life science investors and their portfolio companies including healthcare reform, FDA reform, CMS reimbursement, patent, intellectual property and a variety of small business issues including the SBA's SBIR grant program. She also partners closely with other healthcare related and patient trade groups to help coordinate and leverage key policies and messages important to the advancement of U.S. medical innovation.

Kelly earned her Bachelor of Science Degree at the University of Utah.

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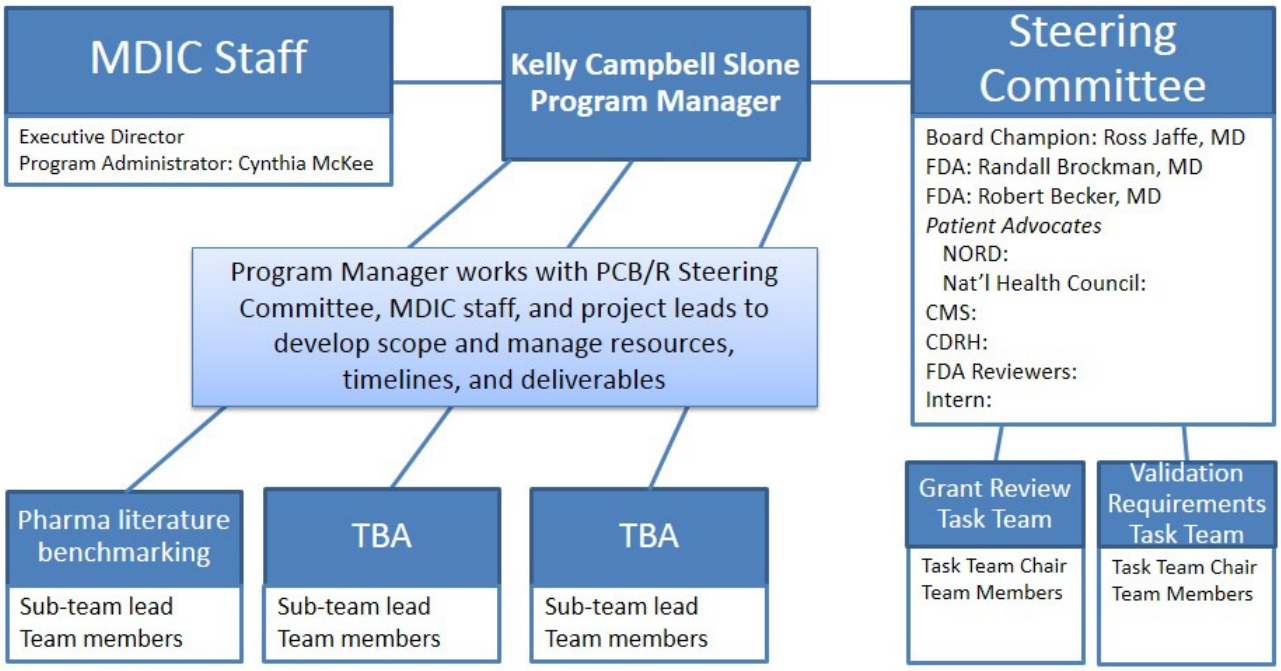
PC B/R Team Structure

Project: Patient Centered Benefit/ Risk



Message from Bill Hawkins, CEO | Immucor
Chairman, MDIC Board of Directors

The MDIC is becoming a reality through the efforts of a lot of people who are committed to ensuring that the industry that we all care so deeply about remains strong in the United States. These people represent private industry, the FDA, CMS, NIH, the academic community and representatives of the patients that depend on our technology. We are proud to be part of focusing the capabilities of the broader community to create a stronger industry for the benefit of all. Please join us in making a reality the following tag line recently adopted by the Center for Devices and Radiological Health:

Faster, Cheaper, Safer

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Clinical Trial Innovation and Reform:
Restoring U.S. Leadership in Clinical Excellence and MedTech Innovation

Charter: Driving a coordinated effort to fundamentally change the methodologies, policies, and expectations for clinical research as necessary to restore the United States to a leadership role in establishing standards for clinical excellence and medical technology innovation; and ensuring that the United States can support first-in-man timelines in the global clinical environment.

Board Champion

Richard E. Kuntz, M.D., M.Sc.
Senior Vice President and
Chief Scientific, Clinical
and Regulatory Officer
Medtronic, Inc.

Dr. Kuntz oversees global regulatory affairs, health policy and reimbursement, clinical research activities, ventures and new therapies, strategy and innovation, corporate development, and acquisitions, integrations and divestitures functions at Medtronic. He is a Co-director, Center for Clinical Investigation, Brigham and Womens Hospital, Boston. He joined Medtronic in 2005. He was the Founder and Chief Scientific Officer of the Harvard Clinical Research Institute, a university-based contract research organization which coordinates National Institutes of Health and industry clinical trials with the United States Food and Drug Administration.

Dr. Kuntz has directed over 100 multicenter clinical trials and has authored more than 200 original publications. He offers a diversified healthcare background and maintains a deep interest in traditional and alternative clinical trial design as well as biostatistics. He served as associate professor of medicine at Harvard Medical School and chief of the Division of Clinical Biometrics. He has been a Director of LifeScience Alley since May 2013 and Tengion, Inc since October 2010.

He completed his residency in internal medicine at the University of Texas Southwestern Medical School, and then completed fellowships in cardiovascular diseases and interventional cardiology at the Beth Israel Hospital and Harvard Medical School, Boston. He received his masters of science in biostatistics from the Harvard School of Public Health. He graduated from Miami University, and received his medical degree from Case Western Reserve University School of Medicine.

Clinical Trial Innovation and Reform (CTIR)

Program Manager

We are in final stages of program manager selection. The individual will be announced shortly.

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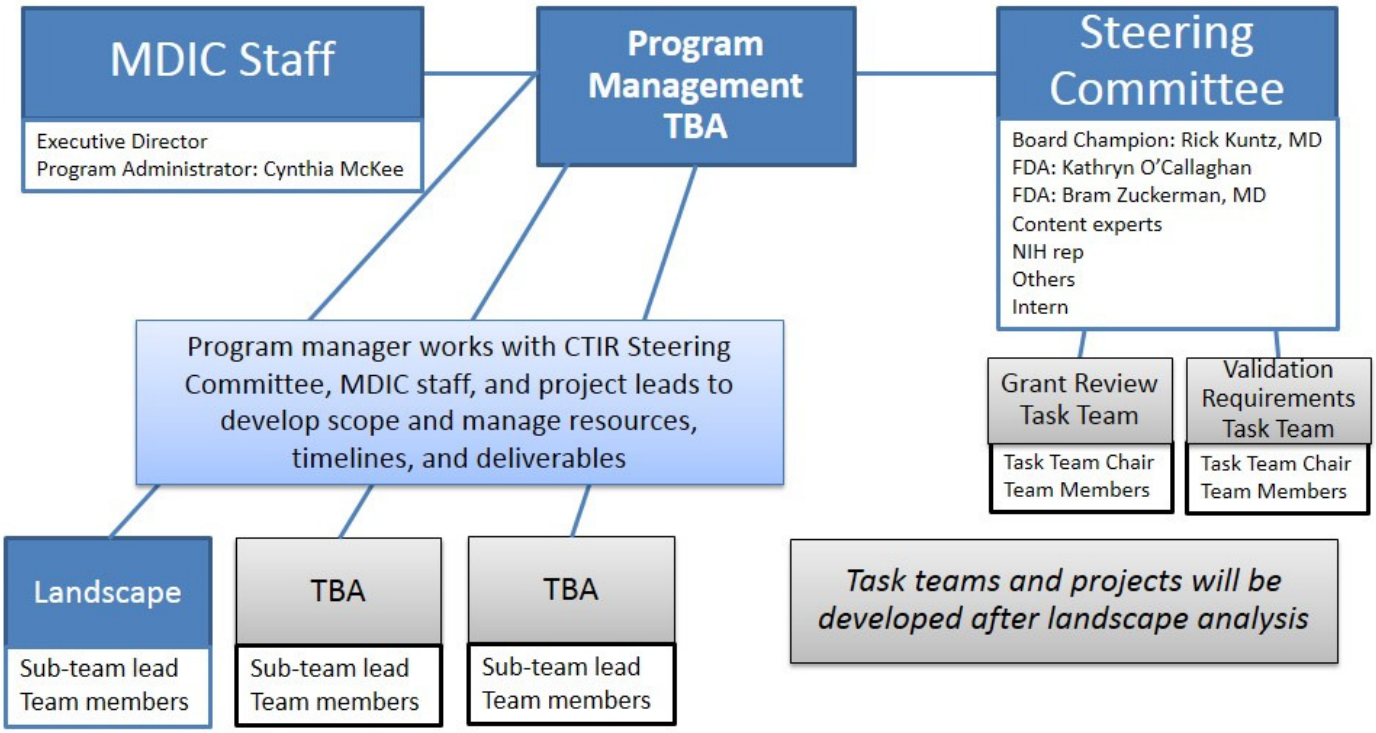
CTIR Team Structure

Project: Clinical Trials Innovation & Reform



Message from Dale Wahlstrom, President and CEO | LifeScience Alley and The BioBusiness Alliance of MN | MDIC Interim Executive Director

MDIC projects are focused in the pre-competitive space. Projects with the broadest impact to the industry have been identified; their outcomes intended to yield tools and processes that can be adopted by the industry at large. The end result will be to help increase the safety and performance of products, reduce the time to market, and reduce the cost of life-enhancing and life-saving products to the health care system. Please join and help keep medical technology strong in the United States.

Updated design and content are live on our new website: www.MDIC.org. Please visit the website and sign up to be on distribution or a member. Both are quick and easy.

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Membership Roster

Abiomed, Inc

AdvaMed

ANSYS

B. Braun Medical, Inc

Becton Dickinson

Biomet, Inc

Bose Corporation

Boston Scientific

Center for Medicare & Medicaid Services (CMS)

Cook Group, Inc

CVRx

Cyberonics

DesignWise Medical

Food and Drug Administration

GE Healthcare

Immucor, Inc

Johnson & Johnson

LifeScience Alley

Medtronic, Inc

National Institute of Health (NIH)

National Organization for Rare Disorders (NORD)

National Venture Capital Association (NVCA)

NAMSA
(North American
Novartis Pharmacuetics

NxThera, Inc

The Pew Charitable Trust

SIMULIA

St Jude Medical

Sysmex Americas, Inc

Terumo BCT

Vital Images, Inc

MDIC Membership

To learn more about the MDIC or to become a member, please visit MDIC.org or contact:

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