Modeling and Simulation (M&S)

Steering Committee

Conference Call Agenda

November 19, 2013
Agenda

1)Welcoming Remarks
   - Michelle McMurry-Heath, Assistant Director for Science, FDA

2)Introductions of the Steering Committee Members
   - 2-4 sentence introduction by each member

3)Regulatory Science at the FDA
   - Kyle Myers, MDIC CM&S FDA PI, Office of Science and Engineering Laboratories, FDA

4)MDIC Overview
   - Dale Wahlstrom, MDIC Emeritus Executive Director & Board Member, Life Science Alley

5)Motivation and Vision of the M&S Program
   - Randy Schiestl, MDIC CM&S Board Champion, Boston Scientific

5)M&S Current Activities
   - Dawn Bardot, MDIC CM&S Program Manager

6)Q&A
• 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.
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
Computational Modeling

From: The Virtual Physiological Human

- Academic, hypothetical
- Catalogue of normal human anatomy
- European Union
- Constructed by: Academics

To: The Virtual Physiological Patient

- Practical, applied to device design and testing
- Catalogue of normal human variation and disease physiology/structure
- FDA
- Constructed by Academics, Industry, FDA
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
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
**MDIC Strategy:**

Create a Public-Private Partnership between Industry, FDA and Non-profits

**PPP Goals**

- Align Resources
- Accelerate Progress
- Achieve Results

- Working cooperatively with FDA to re-engineer pre-competitive technology innovation
- Reducing the time and resources needed for new technology development, assessment, and review
- Helping patients benefit by gaining access to new medical technologies sooner
MDIC Public-Private Partnership

- Collaborative Leadership on Board & Steering Committee from all 3 core groups
- Key technical/clinical/scientific members on working groups
- Focused on common pre-competitive needs

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

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

**Thought Leaders**
- Patient Organizations
- Clinical Research
- Scientific Research

ALIGN | ACHIEVE | ACCELERATE
"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
MDIC Initial Projects

**Patient Centeredness and Benefit-Risk Assessment**

*MDIC Board Champion:* Ross Jaffe, MD | Versant Ventures  
*Program Manager:* Kelly Slone (acting) Stephanie Christopher (11-11-13)

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

**Clinical Trial Innovation and Reform**

*MDIC Board Champion:* Rick Kuntz, MD | Medtronic  
*Program Manager:* Stephanie Christopher (11-11-13)

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

**Computer Modeling and Simulation**

*MDIC Board Champion:* Randy Schiestl | Boston Scientific  
*Program Manager:* Dawn Bardot, PhD

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

## Executive Committee

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<thead>
<tr>
<th>Name</th>
<th>Company/Title</th>
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<tbody>
<tr>
<td>Allan Coukell</td>
<td>The Pew Charitable Trusts Director of Drugs and Medical Devices MDIC Vice-Chair</td>
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<tr>
<td>Vincent Forlenza</td>
<td>Becton, Dickinson and Company President, CEO and Chairman MDIC Finance Committee, Vice-Chair</td>
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<td>William A. Hawkins III</td>
<td>Immucor, Inc. President and CEO MDIC Board Chair</td>
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<tr>
<td>Michael R. Minogue</td>
<td>Abiomed, Inc. President, CEO and Chairman MDIC Secretary; Membership Committee Chair</td>
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<td>William V. Murray</td>
<td>MDIC President &amp; CEO Medical Device Innovation Consortium CEO</td>
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<td>David Perez</td>
<td>Terumo BCT President and CEO Chairman, Blood Management Business Division, Terumo Corporation MDIC Finance Committee Chair</td>
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<tr>
<td>Jeffrey Shuren, MD, JD</td>
<td>CDRH, FDA Director, Center for Devices and Radiological Health Food and Drug Administration MDIC Membership Committee Vice-Chair</td>
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## Full Board

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<tr>
<th>Name</th>
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<tr>
<td>Glenn L. Criser</td>
<td>Biomet, Inc. Senior VP, Quality/Regulatory/Clinical Affairs</td>
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<td>Kathy Hudson, Ph.D.</td>
<td>NIH Deputy Director for Science, Outreach, &amp; Policy</td>
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<tr>
<td>Ross Jaffe, MD</td>
<td>Versant Ventures Managing Director</td>
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<tr>
<td>Richard E. Kuntz, M.D., M.Sc.</td>
<td>Medtronic, Inc. Sr.VP and Chief Scientific, Clinical &amp; Regulatory Officer</td>
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<tr>
<td>Tamara Syrek Jensen, J.D.</td>
<td>CMS Deputy Director, Coverage and Analysis Group</td>
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<tr>
<td>Karen Licitra</td>
<td>Johnson &amp; Johnson Worldwide Chairman, Global Medical Solutions</td>
</tr>
<tr>
<td>Dee Mellor</td>
<td>GE Healthcare Chief Quality Officer</td>
</tr>
<tr>
<td>Daniel J. Moore</td>
<td>Cyberonics, Inc. President &amp; CEO</td>
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<tr>
<td>Michael Rousseau</td>
<td>St Jude Medical Group President</td>
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<tr>
<td>Peter Saltonstall</td>
<td>NORD President &amp; CEO</td>
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<tr>
<td>Joe Selby, M.D., MPH</td>
<td>PCORI Executive Director</td>
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<tr>
<td>Randall Schiestl</td>
<td>Boston Scientific Corporation VP, Global Operations and Technology</td>
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<td>Nadim Yared</td>
<td>CVRx President &amp; CEO</td>
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<td>Dale Wahlstrom</td>
<td>LifeScience Alley and The BioBusiness Alliance of MN President &amp; CEO</td>
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MDIC
Computational 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
CM&S Mission

Quicker and more predictable access for patients to innovative technologies enabled by Computation Modeling and Simulation evidence of safety and performance
TPLC Use of CM&S Evidence

Total Product Life Cycle
Advancing Regulatory Science: Computational Modeling and Simulation in Regulatory Approval

Mission
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.

Approach
Establish Medical Device CM&S Validation Requirements
- Apply Regulatory Science principles to standardize and educate on CM&S V&V.

Facilitate Collaboration on CM&S Research and Application
- Support forums focused on advancing Medical Device CM&S and associated Regulatory Science.

Activate Enabling Research
- Provide seed grants to accelerate the creation of data, processes and knowledge required to verify, validate and apply CM&S to device development and regulation.
- Member companies commit resources to enable MDCI projects

Budget
- Full time Program Manager and associated travel
- Activation grants

Structure
Steering Committee
- Board Champion: Randy Schiestl, Boston Scientific
  - Program Manager: Dawn Bardot, PhD, MDIC
  - FDA PI: Kyle Myers, PhD, Director, Division of Imaging and Applied Mathematics
  - Members

Working Group
- Members and FDA, project teams are sourced from the group

Expert Panel
- Academics and Individual experts resourced as needed

Interested Parties

CY 13 Deliverables
- Steering Committee Finalized
- Computation Model Credibility Determination Methodology
- Request for Proposals Topic Areas Identified

Timeline
- FDA/NIH/NSF Workshop on Computer Models and Validation for Medical Devices
- Program Manager Onboarded
- Finalize Steering Committee Membership
- RFP Announcement
- BOD Approval & M&S Board Champion Named
- FDA PI Identified
- Computation Model Credibility Method Draft

Align • Achieve • Accelerate
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

MDIC Staff
- Executive Director: Bill Murray
- Program Administrator: Cynthia McKee

Dawn Bardot, Ph.D.
Program Manager

Steering Committee
- Board Champion: Randy Schiestl
- Program Manager: Dawn Bardot
- FDA PI: Kyle J. Myers, Ph.D.

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

Expert Panel
- Academia and Individuals
- Team Chair
- Team Members

Grant Review
- Team Chair
- Team Members

* = proposed team member
In Today’s Regulatory Submissions:

• **Modeling is mainly considered a development and design optimization tool**
  - Provides supplemental information-to complement mechanical bench testing

• **Modeling is not a method by which physical performance of final devices is demonstrated**
  - Lack of reporting standards
  - Lack of adequate validation
  - Limited understanding of physiological loads and variations in patient populations
In the Future:

• **Use computer modeling reduce the time and expense of device development and evaluation.**
  - Take the place of some bench and animal testing?
  - Influence clinical trial design?
  - Increase the confidence in the success of the submission?

• **Compendium of anatomic and physiologic models with descriptions of attributes and limitations.**

• **Discrete computer models and simulations validated for regulatory evaluation.**
Priorities

- Confident Decision Making with CM&S
- Collaboration
- Activate Research

• Areas for quick wins
  - Qualify CM&S Credibility Methodology
  - Focus on Non-clinical applications of Regulatory Science
  - Concentrate first on areas with mature CM&S activity to build confidence
Upcoming Activities

• Working Group Large Telecon
  ➢ MDIC Overview
  ➢ Roll of Working Groups
  ➢ RFP Discussions

• Design of Medical Devices Conference
  ➢ Regulatory Science Symposium