Massachusetts Medical Device Development Center (M2D2) Mission

Connect the resources of the University of Massachusetts to Medical Device firms within Massachusetts
Medical Device Industry Critical to Massachusetts’ Future

What was Once An Economic Engine Is Now Declining Compared to Others

Medical Device Employment Trends

Source: Economy.com 4 digit NAICS code 3391 Employment: Medical Equipment & Supplies Manufacturing

With M2D2 They Can Reach Across
FUNDING - History & Needs

$135,000 from S&T (2005)

$150,000 “Pilot” 1 Regional Priority

$500,000 “Catalyst” Project Award 2

1. $1.3 million NIH funding
2. $246,781 in private match
3. $250,000 UMass Lowell & Worcester

Funding History & Needs

Full Implementation Will Require $MM Massachusetts Life Sciences Center

Physical Capacity ($4MM today)

5 Year Program Funding

Self sufficient in Year 6
Product/Business Realization Process
Creates 8-11 Companies/Year

**Phase**
- Screening (2-4 mos) - 15%
- Seed Fund (3-8 mos) - 50%
- Prototype & Animal Trials (12 mos) - 50%
- Human Trials (18-24 mos) - 75%

**Milestone**
- Competitive Selection
- FDA Regulatory Submission
- Prototype demonstrated in Animals/Cadavers
- Seed funding obtained & Business Plan

**Unqualified Leads**
- 300/yr

**Markets & Investors**
- 8-11

**M2D2 Leads**

- **VCs**
  - Brook Ventures, Ned Williams
  - Prism VentureWorks, John Brooks
  - Ironwood Equity, Josh Tolkoff
  - Others

- **UMass System**
  - UMass Medical, Sheila Noone, John Sullivan
  - OTM, Lisa Decker, James McNamara
  - CVIP, Bill Rosenberg, Paul Fredette

- **Other Universities**
  - MITC/MATTO, Abi Barrow
  - CIMIT, Janice Crosby
  - WPI, Grant McGimpsey

- **Mass Hospitals**
  - Partners (CIMIT), Janice Crosby
  - Children's Hospital, Jacqueline Armstrong
  - Baystate Medical Center, David Glass

- **Industry Groups**
  - MassMEDIC, Tom Sommer
  - IGNITE, Laura Allen
  - MDG, Marty Sklar
  - MBI, Kevin O'Sullivan

**Unqualified Leads**
- 300/yr

**Markets & Investors**
- 8-11
M2D2 Steering Committee

- Hooks Johnston, Chair, (SVP, Smith & Nephew, Retired)
- Daniel Baril, President & CEO, Baril Die Company
- Abigail Barrows, Director, Massachusetts Technology Transfer Center, University of Massachusetts President’s Office
- John Brooks III, President & Managing Director, Medical Capital Advisors, LLC
- Thomas Chmura, Vice President for Economic Development, University of Massachusetts President’s Office
- Paul Fenton, Founder, Axya Medical, Inc.
- Robert Halpin, President & CEO, MVEDC, Inc.
- John Konsin, General Manager, Covidien, Inc.
- Peter Litman, President, Julia Therapeutics, LLC.
- Sally Maher, VP Research and Development, Smith and Nephew
- Stephen McCarthy, Co-Director, M2D2, University of Massachusetts Lowell
- Paul Nazzaro, President & CEO, Injectronics Corporation
- Sheila Noone, Co-Director, M2D2, University of Massachusetts Worcester
- Kevin O’Sullivan, President and CEO, Massachusetts Biotechnology Initiative (MBI)
- Richard Packer, President & CEO, Zoll Medical Corporation
- Thomas Sommer, President, MassMEDIC
- John Sullivan, Vice Chancellor for Research, University of Mass. Worcester
- Josh Tolkoff, Managing Director, Ironwood Equity Fund LP
- Mark Trusheim, President, Co-Bio Consulting, LLC
- Edward (Ned) C. Williams III, Partner, Brook Venture Partners

M2D2 Product Realization Process: Prototyping

- Create working medical device ready for testing
- Integrates full range of required expertise
- Provides access to specialized equipment

Core Capabilities

- Design, Fabrication, Materials, Electronics, Analytics
- Wound Healing
- Endoscopy
- Orthopedics
- In Vitro Diagnostics
Stephen McCarthy: Plastics Engineering
  mechanical behavior and fabrication, CAD/CAM
Alan Rux: Electrical Engineering
  electronics and robotics
Xingwei Wang: Electrical Engineering
  biomedical sensors
David Kazmer: Plastics Engineering,
  mold engineering & control systems
Christopher Niezrecki: Mechanical Engineering,
  design, smart materials, signal processing
Hongwei Sun: Mechanical Engineering,
  microfluidics devices for drug delivery and diagnostics, MEMS
  lab, microfabrication

M2D2 Medical Expertise (Worcester)

• Sheila Noone, Director of Clinical Research Operations
  and Oversight

• Surgical Expertise
  – Demitrius Litwin, MD, Chair of Surgery
  – Ray Dunn, MD, Chief of Plastic Surgery
  – Richard Beane, Director of Research - Endoscopic
    Surgery
  – KC Balaji, MD, Chief of Urology

• Orthopedic Expertise
  – David Ayers, MD, Chair
  – Pat Franklin, MD, Director, Clinical Outcomes Research

• Babs Soller, PhD, Professor, Department of Anesthesia

• Abraham Morse, MD – Urogynecology

• James McNamara, PhD, Executive Director, Office of
  Technology Management
M2D2 Business Realization Process:

M2D2 Venture and Innovation Lab
- UML College of Management,
- Partner honors students with M2D2 companies to assist with business realization activities from incubator to spin-off phases of development

MassMEDIC
- Partners a medical device CEO or senior executive who will serve as the entrepreneur's personal coach through an 8- to 16-week process
- Help each entrepreneur hone his or her business model and build a compelling case to present to potential investors

UML Commercial Ventures
- Business Incubator
- $80M plus in venture capital since 1998

M2D2 Education Process

Biomedical Engineering & Biotechnology Graduate Degree Program (UMass System)
- UMass Boston Dr. Manickam Sugumaran
- UMass Lowell Dr. Bryan Buchholz
- UMass Worcester Michael Cole
- UMass Dartmouth Dr. Alex Fowler

MassMEDIC
Medical Device Design and Engineering Certificate Program
M2D2 Biomedical Expertise (Lowell)

- Bryan Buchholz, Professor, Work Environment & Director, BioEngineering
- Kathleen Doyle, Professor & Chair, Clinical Laboratory and Nutritional Sciences
- Carl Lawton, Professor, Chemical Engineering
- Catherine Galligan, Project Manager, Sustainable Hospitals Project
- Jerry Hojnacki, Professor (former Dean of Graduate School)

Year 1 Companies

- Perfusion Technology (2 SBIR’s)
  Ultrasound Enabled Drug Delivery To the Brain
- Spire Biomedical (1 SBIR)
  Novel Dialysis Catheter
- Schena Ostomy Technologies
  Flushable Ostomy Bag
- Anterios
  Transdermal Delivery
- Metabolix
  Biodegradable Plastics
  Recently completed IPO
M2D2 Funding

$150,000 “Pilot” (2007)

Submitted 7 STTR/SBIR
1 Awarded, 1 Will be Awarded, 1 Probable, 2 Rejected, 2 Pending

Multiple Companies Already Benefiting

- VasoTech
  Worcester, MA
  (FastTrack, April 2007)
  (STTR, April 2007)

  Biodegradable
  Drug Eluting Stent

  Will Fund
  $1.2 Million
Multiple Companies Already Benefiting

• Kazak,
  Woburn, MA
  (STTR, April 2007)

  **Portable “Jaws of Life”**

  Funded $100,000

Multiple Companies Already Benefiting

• **Vista Scientific**
  Andover, MA
  (STTR, April 2007)

  Nanosphere-Antibiotic Corneal Contact Lens Delivery System

  Probable Funding $100,000
Multiple Companies Already Benefiting

- **BosteQ**
  Boston, MA
  (STTR April 2007)

Vibrotactile Tilt Feedback Belt

for Balance Rehabilitation and Elderly Fall Reduction

- **BosteQ**
  Boston, MA
  (STTR August 2007)

“Smart Sock”

for Balance Rehabilitation and Elderly Fall Reduction
Multiple Companies Already Benefiting

Oz Technologies
Baystate Health Care
Springfield, MA
(STTR, Dec 2007)

User Friendly Pessary

JAll $500K “Catalyst” Grant

- Proof of “E-Z Pass” Concept resulting in 1 new product/company

Three Phase Development Process

1. Competitive Selection
2. Concept Sources
3. Prototype demonstrated in Animals/Cadavers/Humans for FDA Regulatory Submission
4. Seed funding obtained & Business Plan
5. Prototype
6. Seed Fund
7. Screening
8. Concept Sources
9. Competitive Selection

Phase

Screening
Seed Fund
Prototype & Trials
Concept Sources

Milestone

Markets & Investors

Three Phase Development Process
# Next 15 Leads in Pipeline

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<thead>
<tr>
<th>Company</th>
<th>Product</th>
<th>Contact</th>
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<tr>
<td>Aurora</td>
<td>Selling Hemostat</td>
<td>Javier de Luis</td>
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<tr>
<td>SonoMedical, Inc.</td>
<td>Senses Blood Flow Turbulence as a means of detecting CAD</td>
<td>John Reichenbach</td>
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<td>Enhanced Medical Systems, LLC</td>
<td>Heartlander</td>
<td>Dwight Meglan</td>
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<td>Magenta Medial Corporation</td>
<td>Clampless Coronary Artery Bypass Graft [CABG] Surgery</td>
<td>Dr. Aaron Kaplan</td>
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<td>BioTrove, Inc.</td>
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<td>Albert A. Luderer</td>
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<td>Veraxa Health, Inc.</td>
<td>JoslinVision Network (JVN)</td>
<td>Richard J. Morello</td>
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<td>Corum Medical, Inc.</td>
<td>Lumen/</td>
<td>Alan Lifsitz</td>
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<td>HyperMed, Inc.</td>
<td>OxyVu™</td>
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<td>Heartflow™</td>
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<tr>
<td>St. Elizabeth’s Medical Center</td>
<td>A Novel Intracardiac Injection Catheter</td>
<td>Tengiz Tkebuchava</td>
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<tr>
<td>St. Elizabeth’s Medical Center</td>
<td>Novel Biventricular Pacemaker Lead</td>
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<td>Harvard Medical School</td>
<td>Pneumatic Knee Brace</td>
<td>David Hunter</td>
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<td>SynTrend</td>
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<td>Minna Levine</td>
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# Life Sciences Collaborative

- Advising Patrick Admin. on Life Sci. Legislation

# Regional Innovation Centers

- Chaired by Chris Gabrieli

- Strong academic core
- Medical/clinical
- Prospect of business & commercialization
- Private-sector matching
- Science and business
- Shared use facility
M2D2 Innovation Center for Life Sciences

- Concept Screening
- Business Plan Development
- Seed Financing
  - SBIR/STTR Grant Identification and Winning
  - M2D2 Financing
- Product Accelerator Space (30K Sq. Ft. IPI Building)