

Leveraging Resources for Medical Device Development

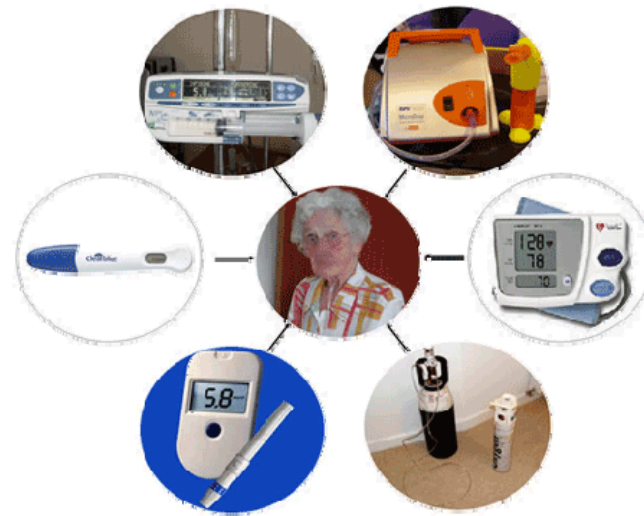
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Mass. Life Science Cluster

- Biotechnology
 - Pharmaceuticals
 - Clinical Research
 - Medical Devices
-
- Nanomanufacturing & Nanosensors, platform technology for diagnoses and delivery.



Mass. Life Science Cluster Job Creation

BASIC RESEARCH

SCIENCE

Ph.D Biology,
Chemistry,

BS, MS
Research Assts.

Lab Technicians

APPLIED RESEARCH

SCIENCE & ENGINEERING

PhD Researchers

MD, Clinical
Researchers

Research Assts.

Statisticians

Clinical Lab
Technicians

PROTOTYPE & DEVELOPMENT

ENGINEERING, REGULATORY & BUSINESS

Engineers

NPD/ Operations
Specialist

Regulatory

QA/QC

Technicians

COMMERCIALIZATION

BUSINESS

Marketing

Medical Affairs

Brand Managers

Manufacturing

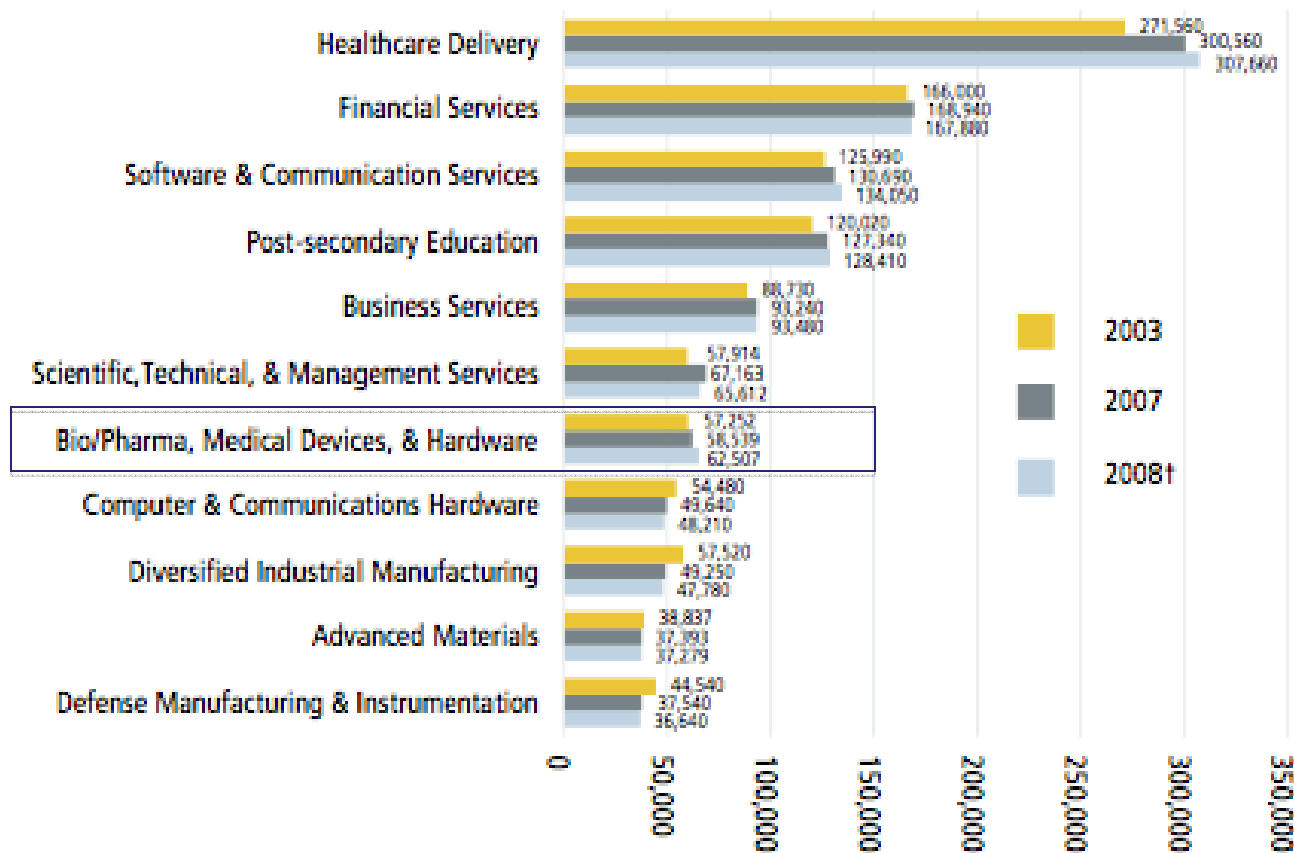
Sales

Impact of Medical Device Companies on Mass.

- 225 Medtech Companies
- Employ approx. 55,000 people
- 10% of Mass. Exported Goods - \$7.2 billion annually
- Med. Device companies relatively small (< \$30 mil annual revenue)
- Several very large companies
Boston Scientific, Philips, Genzyme, etc.

Mass. Life Science Cluster

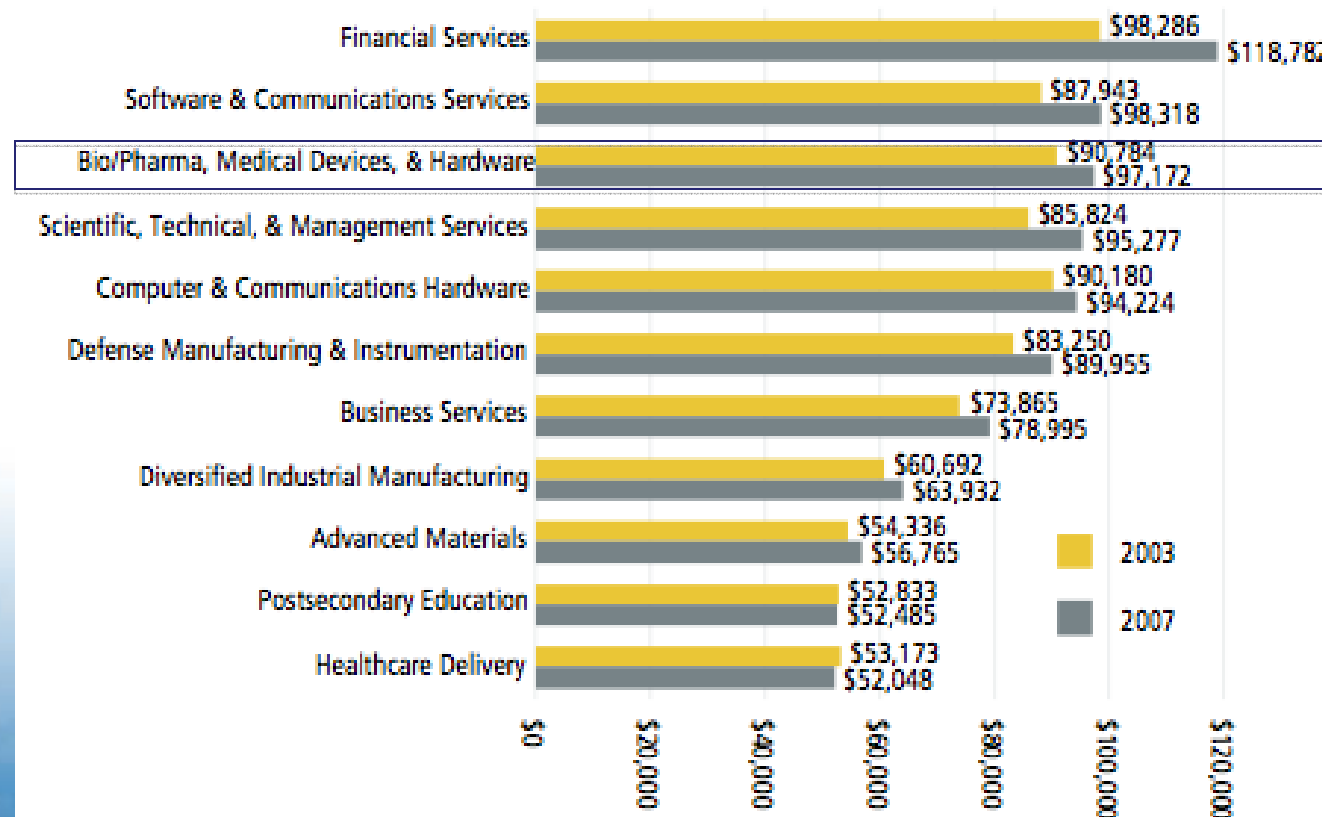
Total employment by industry cluster, Massachusetts, 2003, 2007, and 2008†



Source: Moody's Economy.com (†2008 estimated in October 2007)

Mass. Life Science Cluster

Average annual wage by cluster, in 2007 dollars,
Massachusetts, 2003 and 2007



Source: Bureau of Labor Statistics

What Resources are Required for Medical Device Development?

- -
 - Money
 - Engineering Talent
 - Clinical Skills/Labs
 - Customers/Markets
 - Lawyers
 - Work Force
 - Others
- Depends on
 - Device
 - Phase of Development
 - Business Strategy

What Resources are Required for Medical Device Development?

- Device
 - Class I, II, III – different regulatory paths
- Phase of Development



- Strategy
 - New Product, New License, or New Business

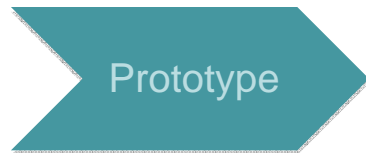
Regulatory Path – As of Today

- **Class I Device**
 - Minimal potential harm to user. History of safe use, Most Exempt Pre-Market Notification (e.g., tongue depressor, sling),
- **Class II Device**
 - Methods/Standard exist to ensure safety
 - Pre-market notification, FDA 510 (k) Clearance
 - Predicate Devices (e.g., monitor, x-ray system)
- **Class III Device**
 - Support or sustain life, high degree of risk
 - Pre-Market Approval, Inspection

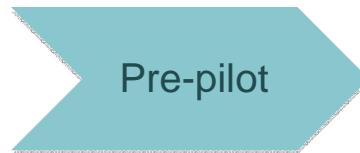
Phase of Development



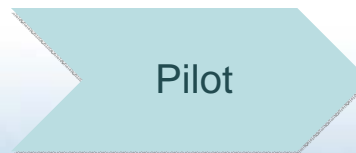
- Scan Business Oppty., Medical Feasibility, IP, Clinical Path



- Initial Design & Engineering, Tech. Feasibility, IP Review

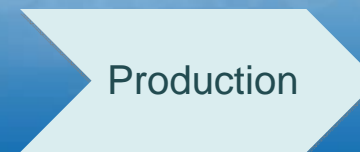


- Usability, Market Analysis, Clinical Plan, Business Strategy



- Prototype Eval., IP Review, Manufacturing, Clinical Validation, Regulatory Submission, Reimbursement Update

- Dependent on Business Strategy
Manuf., Distr., Training, QA, HR



Business Strategy

- Do you want to start and run a company?
- Do you want to license your idea, concept or prototype?
- Do you want to add a new product or product line?
- Each requires different skills, resources & commitment.

What Resources are Required for Medical Device Development?

- Yes, it depends on the Device, Stage of Development and Business Strategy, but...
- Funding and Talent are Critical!

Sources of Funding

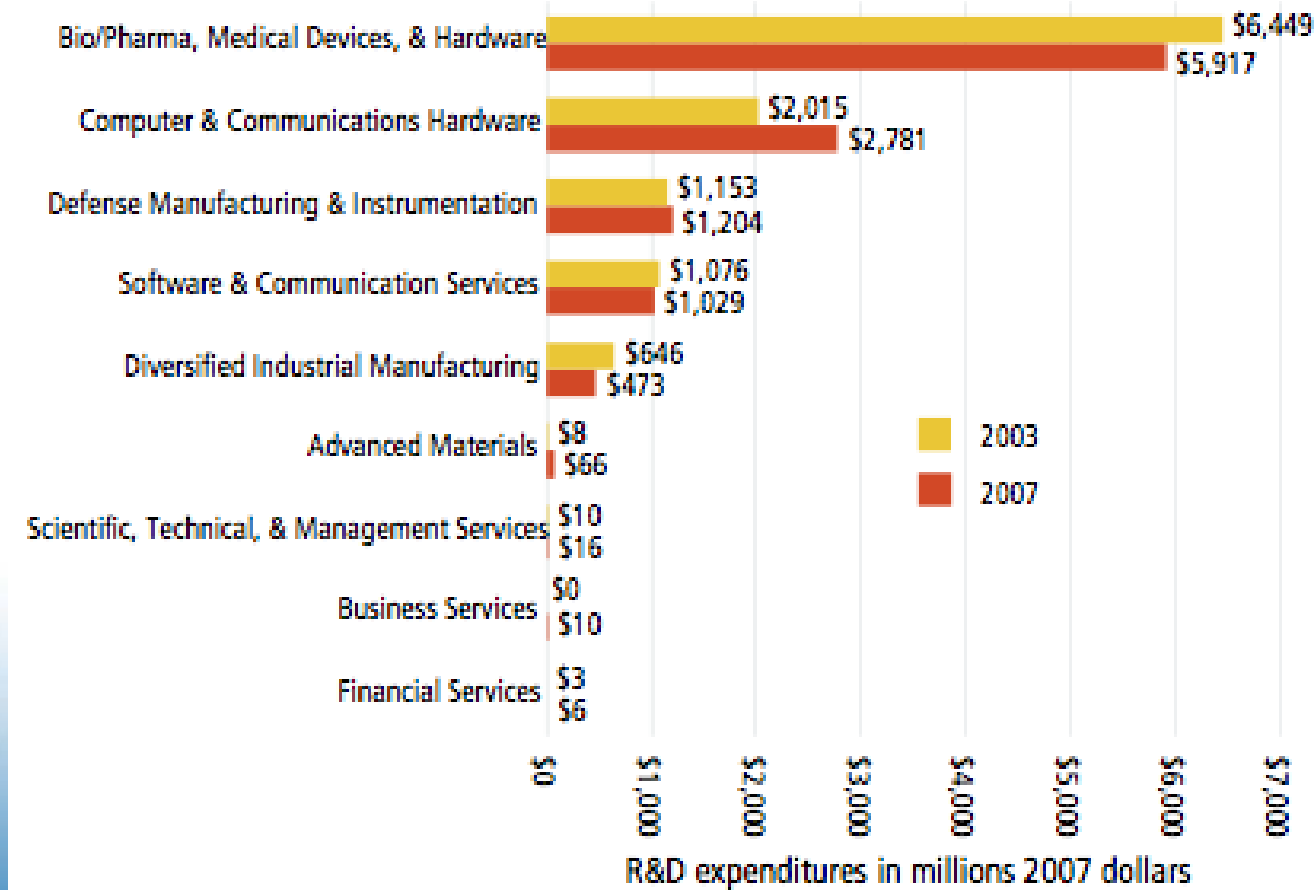
- Federal Grants
- Industry Sponsored Research
- Corporate R&D
- Licensing Royalties
- VC Funds
- Other

SBIR_STTR Grants

- Small Business Innovation Research
 - \$75.8 M to Mass., 2009
 - Grant to small business for “proof of concept” research (Phase I) & developmental research towards commercialization (Phase II)
 - 11 Federal Agencies
- Small Business Technology Transfer
 - Small business must partner with federally funded research institution
 - DOD, DOE, NASA, HHS, NFS
 - Up to \$850,000 (Phase I & II)

Corporate R&D

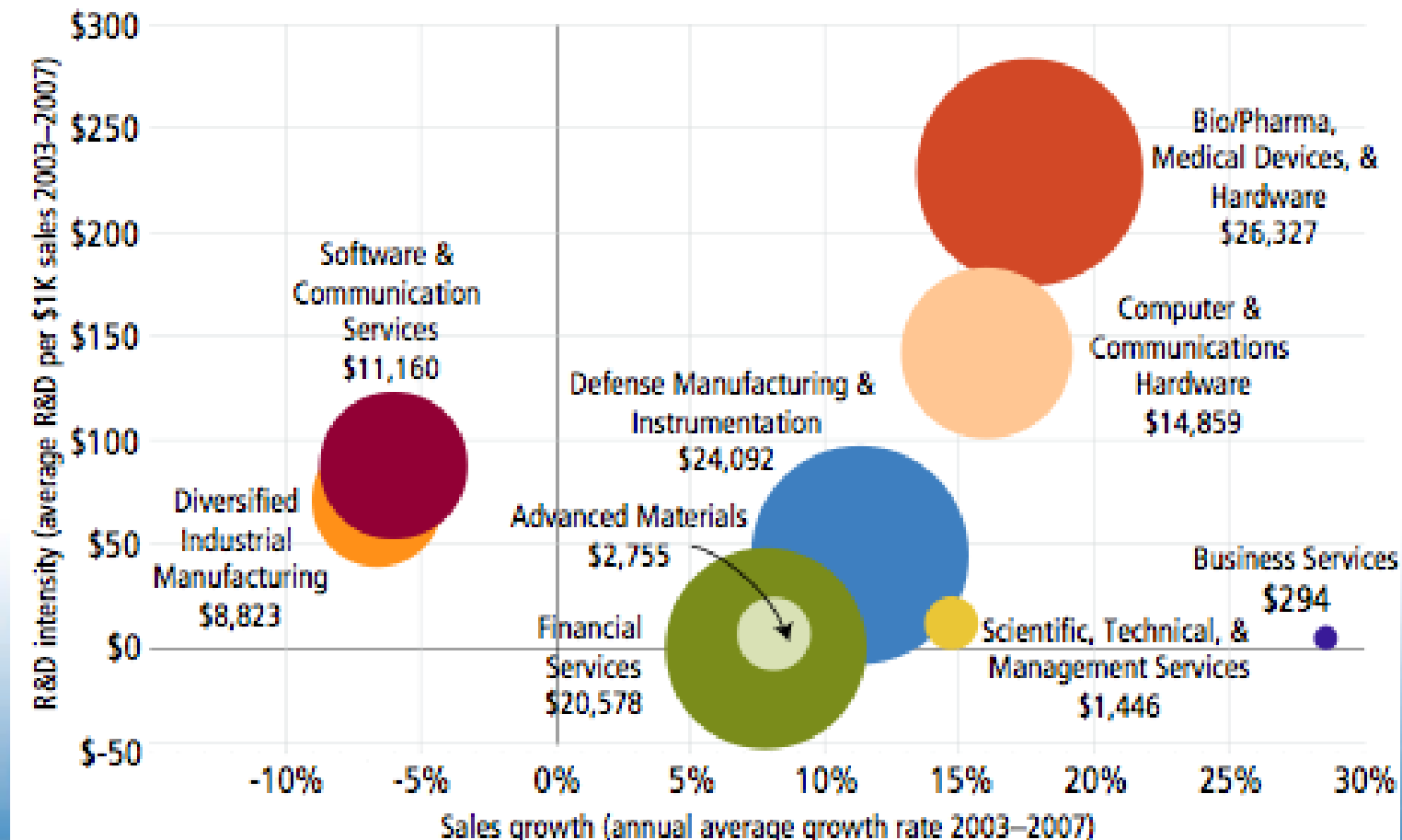
Corporate R&D expenditures by industry cluster,
Massachusetts firms, 2003 and 2007



- MTTTC/JAII Index of MA Innovation Economy

Corporate R&D

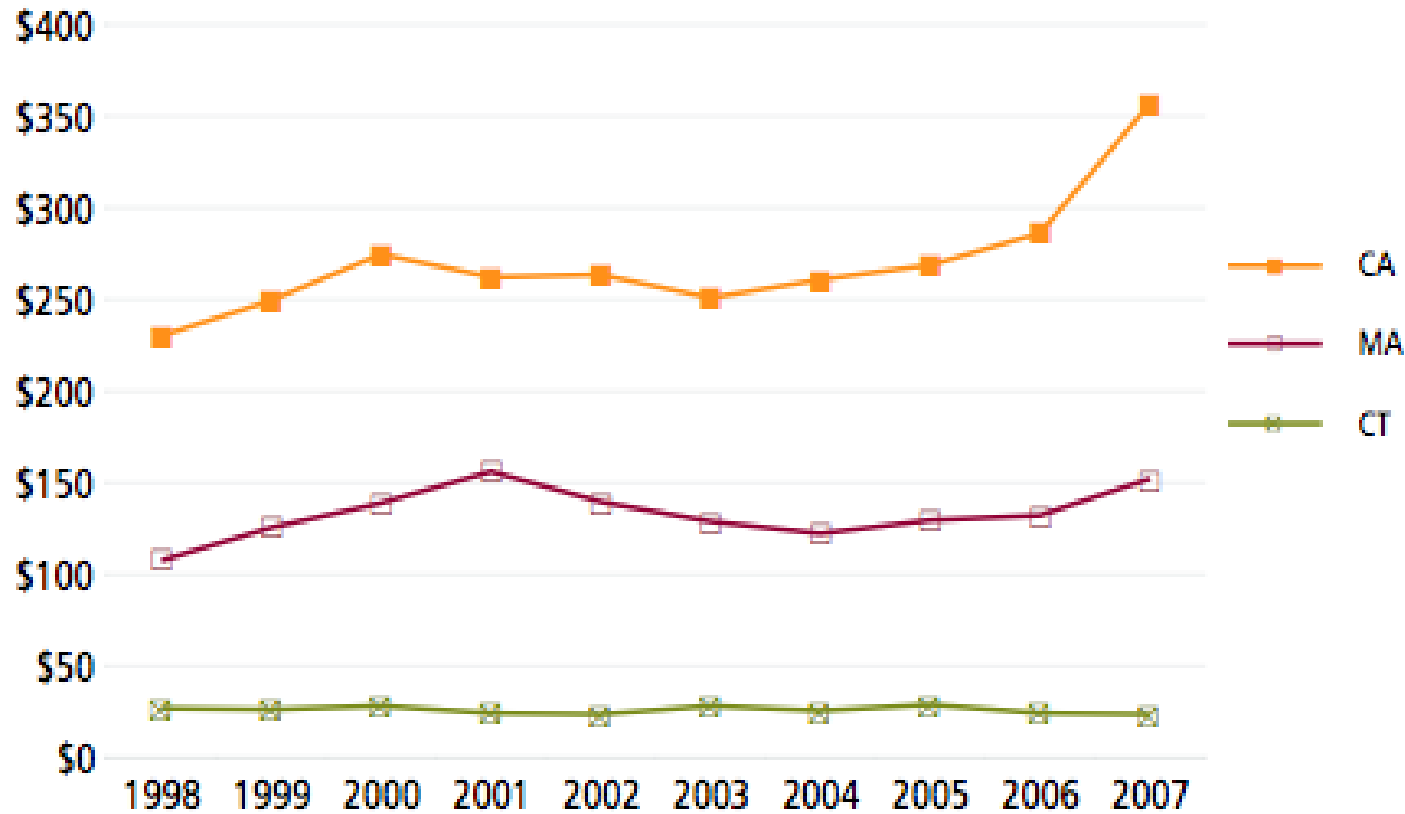
Corporate R&D intensity and sales growth by industry cluster, Massachusetts, 2003 and 2007



- MTTTC/JAII Index of MA Innovation Economy

Industry Sponsored Research

Industry funding of academic research, LTS, 1998–2007

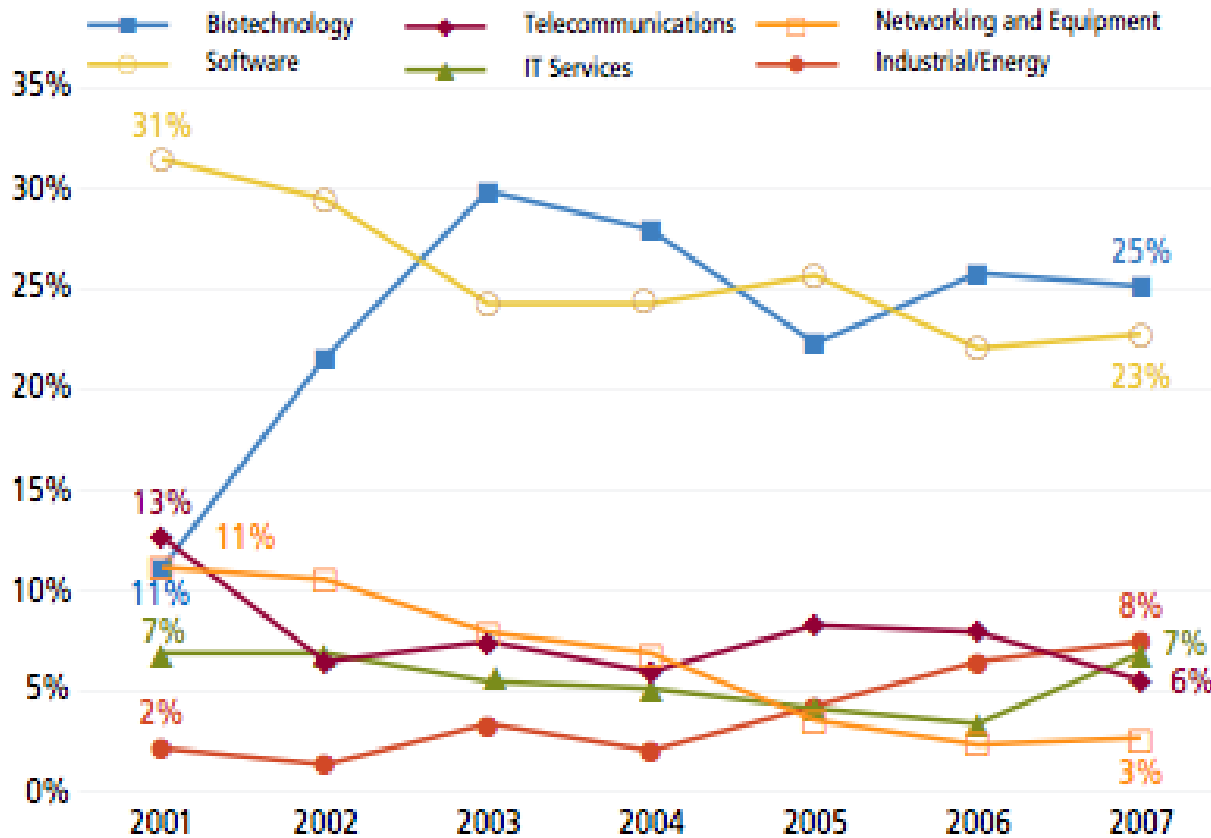


Source: National Science Foundation

- MTTTC/JAII Index of MA Innovation Economy

Venture Capital Investment

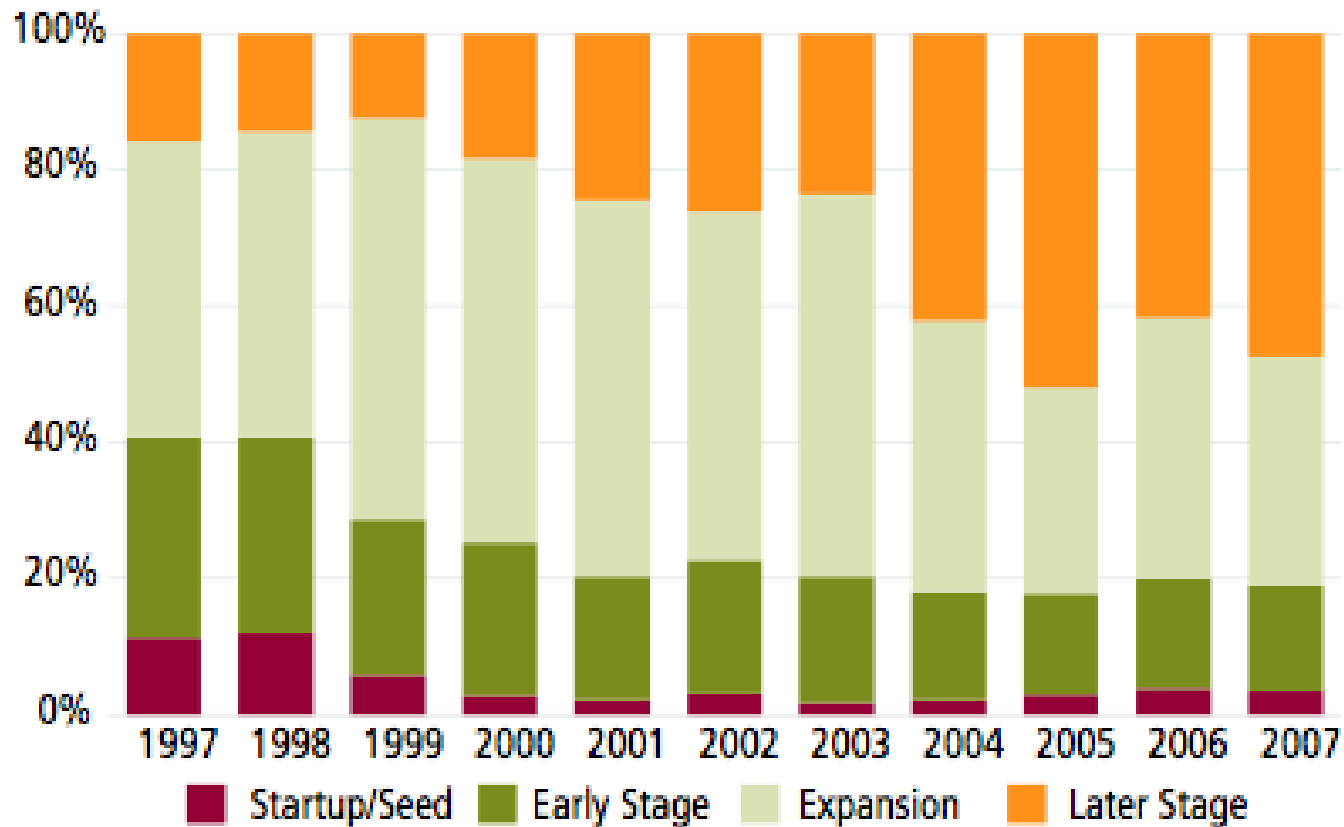
Venture capital investment percentage by sector, Massachusetts, 2001–2007



- MTTTC/JAII Index of MA Innovation Economy

Venture Capital Investment

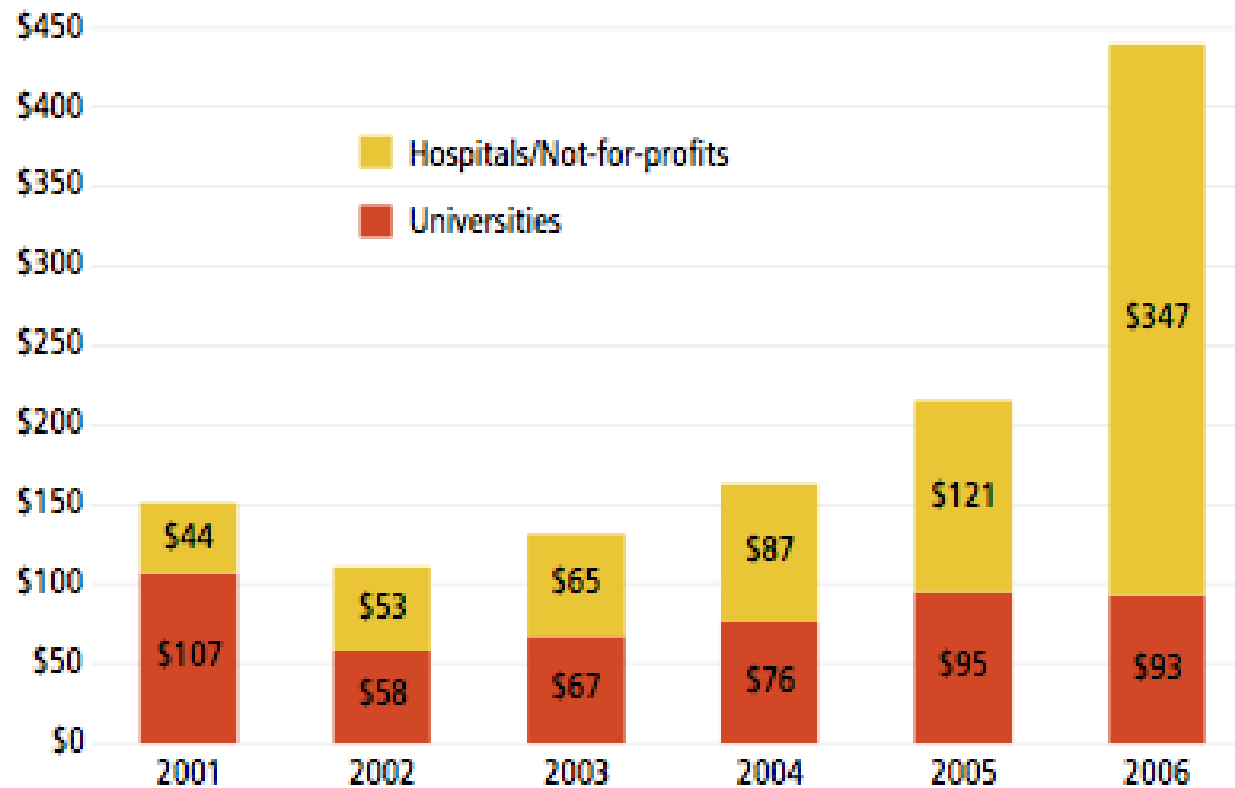
Venture capital investments by stage of financing,
Massachusetts, 1997–2007



- MTTC/JAI Index of MA Innovation Economy

Licensing Revenue

Technology licensing revenue for major universities, hospitals, and other not-for-profit research institutions, Massachusetts, 2001–2006



Source: Association of University Technology Managers

- MTTC/JAIL Index of MA Innovation Economy

Sources of Talent

- **M2D2**

- Concept to Prototype, Resource Network
- Business, Clinical, Engineering Assistance
- Incubator



- **Massachusetts Life Sciences Center**

- Research Funding, Accelerator Funding
- Infrastructure Support, Summer Intern Program



- **MassMEDIC**

- MedTech Ignite
Mentoring by Experienced Med Tech Execs,
Education programs



Sources of Talent

- Mass. Technology Transfer Center

- Platform Presentation
- Entrepreneur/Inventor Training
- Revolving Grants Program



- Massachusetts Technology Collaborative
John Adams Innovation Institute

- Support Innovation activities across industry sectors in Mass.
- IT/Wireless, Life Sciences, Medical Devices

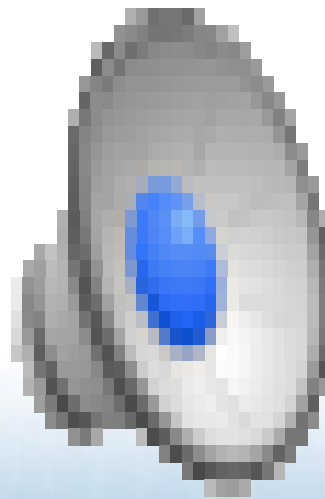


- MVVF: Merrimack Valley Venture Forum

- Promote regular meetings among entrepreneurs, inventors, funders and related support personnel
- Recent launched first business plan competition



Can We Maintain Our Lead In This Industry Sector?



University of
Massachusetts
UMASS Lowell

Can We Maintain Our Lead In This Industry Sector?

- What do you think?

