20+ Years of Boston's Clinical Innovation Culture

Kirby G. Vosburgh, PhD

MASSACHUSETTS GENERAL HOSPITAL
BRIGHAM AND WOMEN'S HOSPITAL
HARVARD MEDICAL SCHOOL

About this Talk

- At IMAGINE 2016, I presented a talk entitled "How to Best Achieve Innovation in a Multi-Institute Town: Comments based on experiences in Boston."
- Today's presentation describes the structures and organizations that comprise the culture in which that work has been done. Copies of the 2016 talk are available; send an email to (kirby@bwh.harvard.edu)

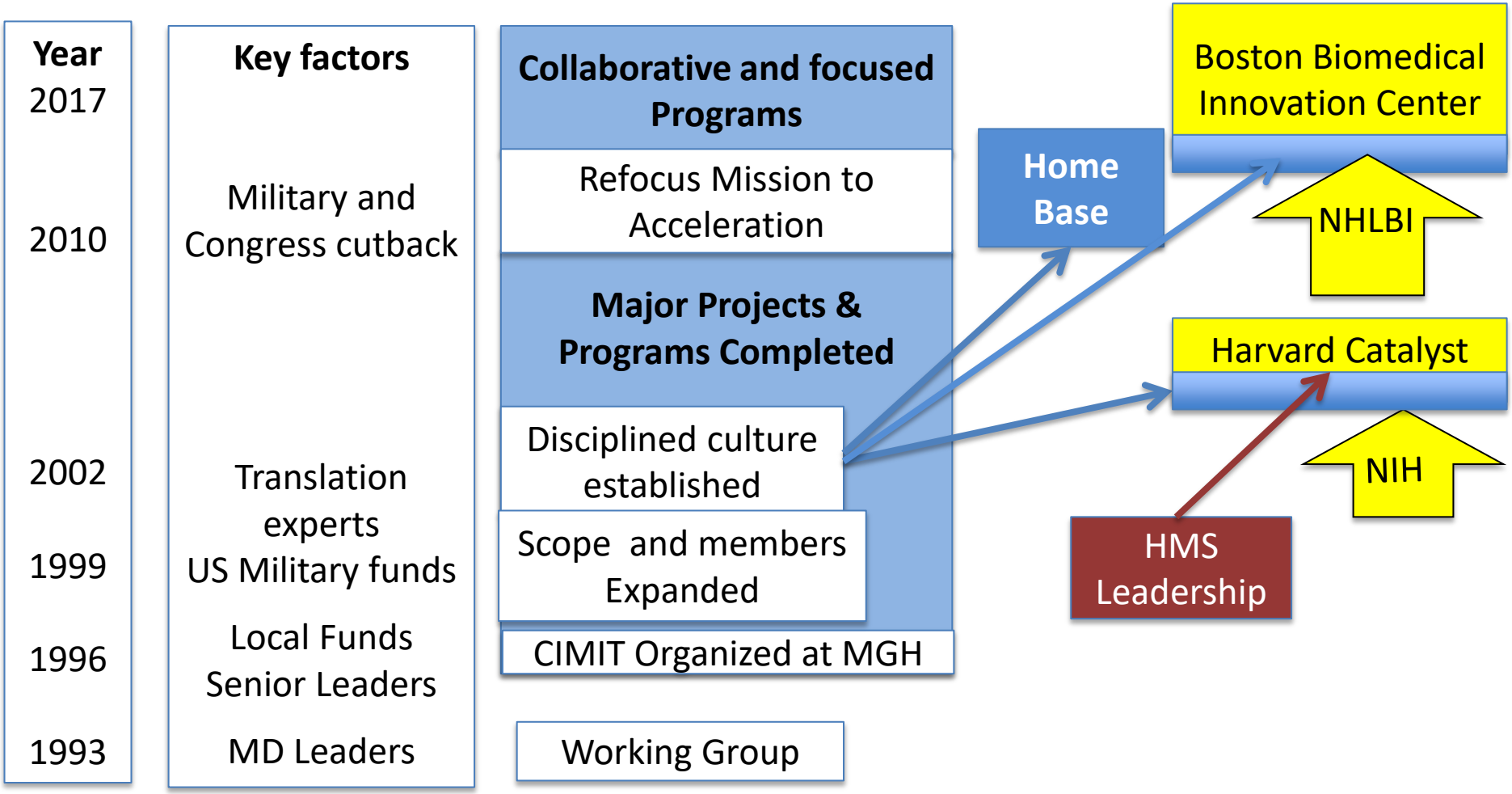
Host Culture

- There is a lot of activity in Boston. At Harvard alone, the Medical School Faculty numbers over 11,000 people. They supervise almost 9000 fellows and residents.
- The technical universities, led by MIT, and Boston University, Northeastern, and many others, have a long tradition of supporting translational research.
- Here we focus on organizations whose goal is insertion of technology into clinical practice. This being Boston, my apologies for those I left out.

Organizations to be Discussed

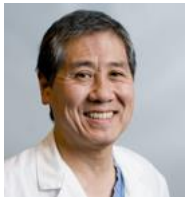
- CIMIT (1997) Now called the Consortia for Improving Medicine with Innovation and Technology; based at Mass General.
- Harvard Catalyst (Harvard Clinical and Translational Science Center-2008). Funded by the NIH Clinical and Translational Science Awards (CTSA) Program
- Home Base (2009) conducts care and research on TBI and PTSD. Funded by Boston Red Sox Foundation and MGH.
- B-BIC (2013) The Boston Biomedical Innovation Center, is a multi-institutional organization based at BWH. Funding is from the NIH/NHLBI and B-BIC members

CIMIT and Recent Organizations

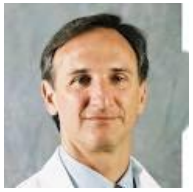


Originators of the CIMIT Concept

David Rattner MD
General Surgeon



Norman Nishioka, MD
Gastroenterologist

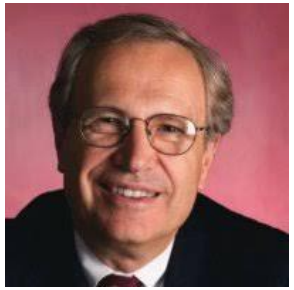


Keith Isaacson, MD
Gynecologist

Steven Dawson, MD
Interventional Radiologist

- The first meeting of this informal working group was convened by Dr. Rattner in 1993. The participants were motivated to find common ground for future procedures.
- Example: the rapid success of laparoscopic techniques in general surgery (although the gynecologists had been using similar concepts for some years).
- Their work had two big results:
  1. It laid the foundation for physician-technologist collaborations which became the key principle of CIMIT,
  2. It laid the foundation for leadership developments from 2001-2010 of advanced methods for less invasive and image guided procedures.

CIMIT Leadership

- 1996: MGH supplied funding and recruited John A. Parrish, MD and Ronald Newbower, PhD to lead CIMIT
  - Originally: The Center for Innovative Minimally Invasive Therapy
- They reached out to partner institutions
  - MIT
  - Brigham and Women's
  - CS Draper Laboratories
  - Partners Healthcare
- Running rules for Intellectual Property ownership and accounting standards were developed and enforced.

Mission

- When significant scale funding was received from the US military, CIMIT implemented a culture based on "finding, funding, and facilitating" innovative projects which were multidisciplinary, multi-institutional, and directed toward significant clinical impact.
- From the beginning, the military endorsed this broad application space. Resources were also devoted to developing technologies that served military needs.

Structure

- CIMIT brought on board several experienced clinical and technology leaders to encourage and support projects, and form the core of an education program which sponsored regular multidisciplinary seminars and training programs.
- “Site Miners” were recruited, with support from each collaborating institution, to find potential innovation leaders and help them build projects.

Maturity

- By 2003-4, CIMIT had fully staffed facilitation offices, an established culture to select only the highest quality projects, and excellent relationships with its funding agencies and host institutions.
- By 2007, CIMIT had received total funding of over $113M (USD), and established development programs in:
  - Biomaterials and Tissue Engineering
  - Cardiovascular Disease
  - Simulation
  - Image Guided Therapy
  - Global Health
  - **Minimally Invasive Surgery**
  - Trauma and Casualty Care
  - New Initiatives

A CIMIT Success Story: Minimally Invasive Therapy

- MGH was convinced to build a novel experimental procedure room: the Operating Room of the Future.
- The goals were to improve efficiency, safety, and reduce crowding. It featured separate anesthesia induction and recovery suites, a patient transport table with full monitoring, integrated displays and procedure tracking systems, and observation room for technical support.
- Ten industrial partners participated directly.
- In addition, the patient flow and procedures were simulated in realistic mock up rooms; this had a direct positive impact on patient safety.
- The goals were met.

Long Term Results of the Advanced Surgery Program

- The learnings were applied in the building of OR suites recently opened at MGH

- Spinoffs included:
  - World leadership in Natural Orifice Endoscopic Translumenal Surgery (NOTES) procedures and technologies.
  - The Medical Device Plug and Play Program

NOTES

David Rattner, MD and colleagues

The logical next step beyond laparoscopic surgery is Natural Orifice Translumenal Endoscopic Surgery (NOTES). Beginning in 2005, CIMIT supported:

- An $800K+ internal program focused on technology demonstrations led by Drs. Rattner and Christopher Thompson (a gastroenterologist).
- An outreach program that involved multiple sites and key vendors. Universal technical goals were developed.* This is still led by the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

* Rattner, D, Kalloo, A. "ASGE/SAGES working group on natural orifice translumenal endoscopic surgery." *Surgical Endos.& Other Interventional Tech.* 20.2 (2006): 329-333.

Medical Device Plug and Play

(MDPnP, Julian Goldman, MD)

- **The Problem:** How can we better use medical devices to improve the safety of care?
- **The Answer:** Facilitate the adoption of open standards and interoperable technologies to integrate clinical environments.
- **Side Benefits:** Lower Cost, Improved Reliability, reduce Physical Clutter
- **What it's not:** MDPnP does not seek access to proprietary "value added" algorithms embedded in devices. The family jewels are safe.

Get involved at www.mdPnP.org

MDPnP Goals

- Create Safe Systems
  - Safe interoperability
  - Equipment can't be just from one vendor. Consumers want to use components from various manufacturer.
  - Need apps that build on data from different devices, but no company has resources to do the apps
- Compensate for Noisy Data
  - Make system safer by combining smart signals
  - Need algorithms to say what seems to be going on.
  - Compensate for caregiver "blind spots."

Open Integrated Clinical Environment (ICE)

- The MD PnP Program has developed an open source implementation of the ICE standard and made it freely available on SourceForge. We believe that this OpenICE implementation will reduce the time and cost of performing clinical studies.
- The platform includes software adapters for anesthesia machines, ventilators, and patient monitors, etc., OMG DDS standard middleware, and demonstration applications.
- Applications can be built on this platform to implement smart alarms, physiologic closed-loop control algorithms, data visualization, and clinical research data collection.
- A user/developer community is now active.

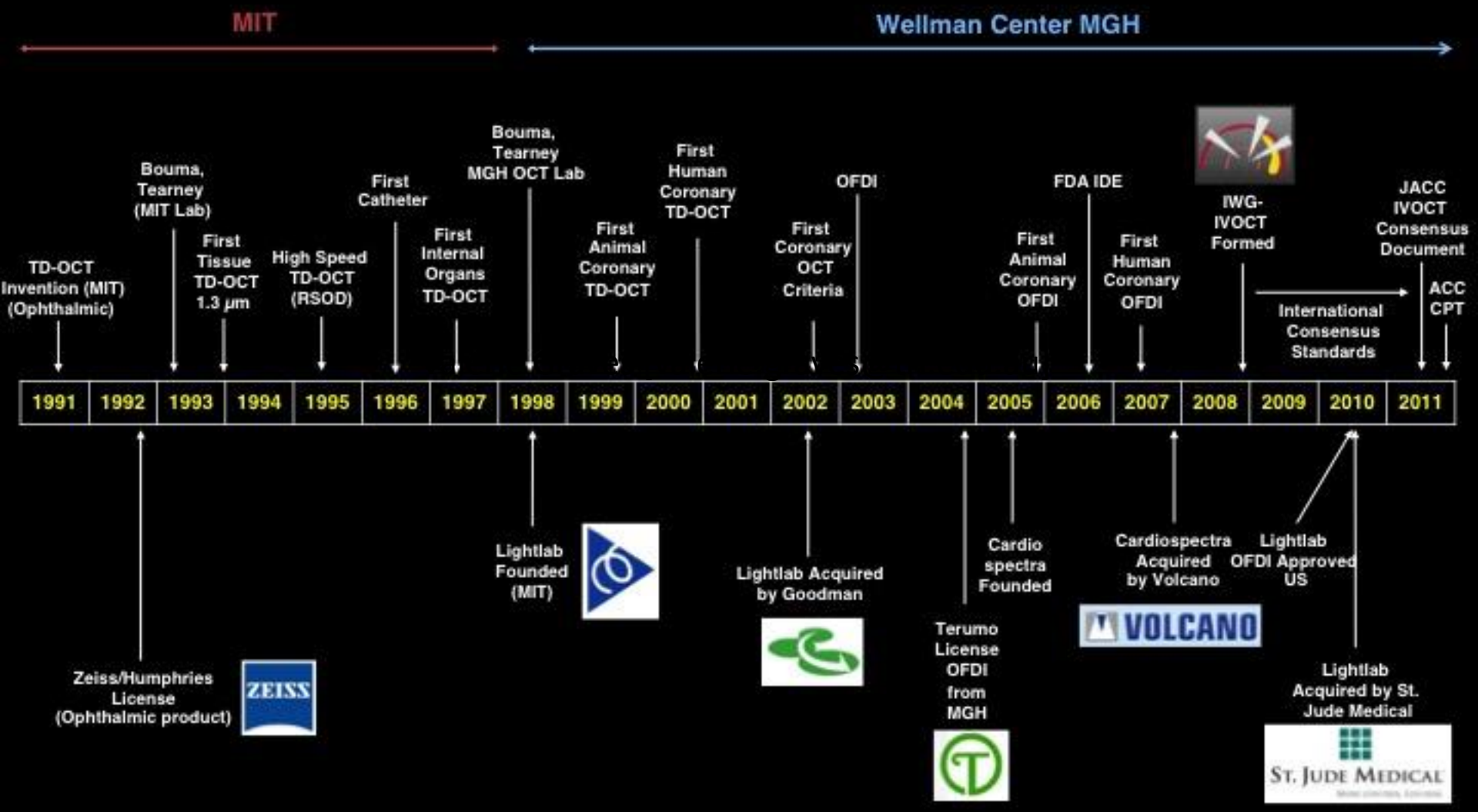
Quantum Medical Device Interoperability (QDMI)

- The MD PnP Program received a $10M NIH Phase II Quantum Grant in 2010 for the development of a prototype healthcare intranet for improved health outcomes. Components include:
  - Clinical Scenarios & Use Cases
  - Requirements
  - Software & Architecture
  - Test & Validation Tools

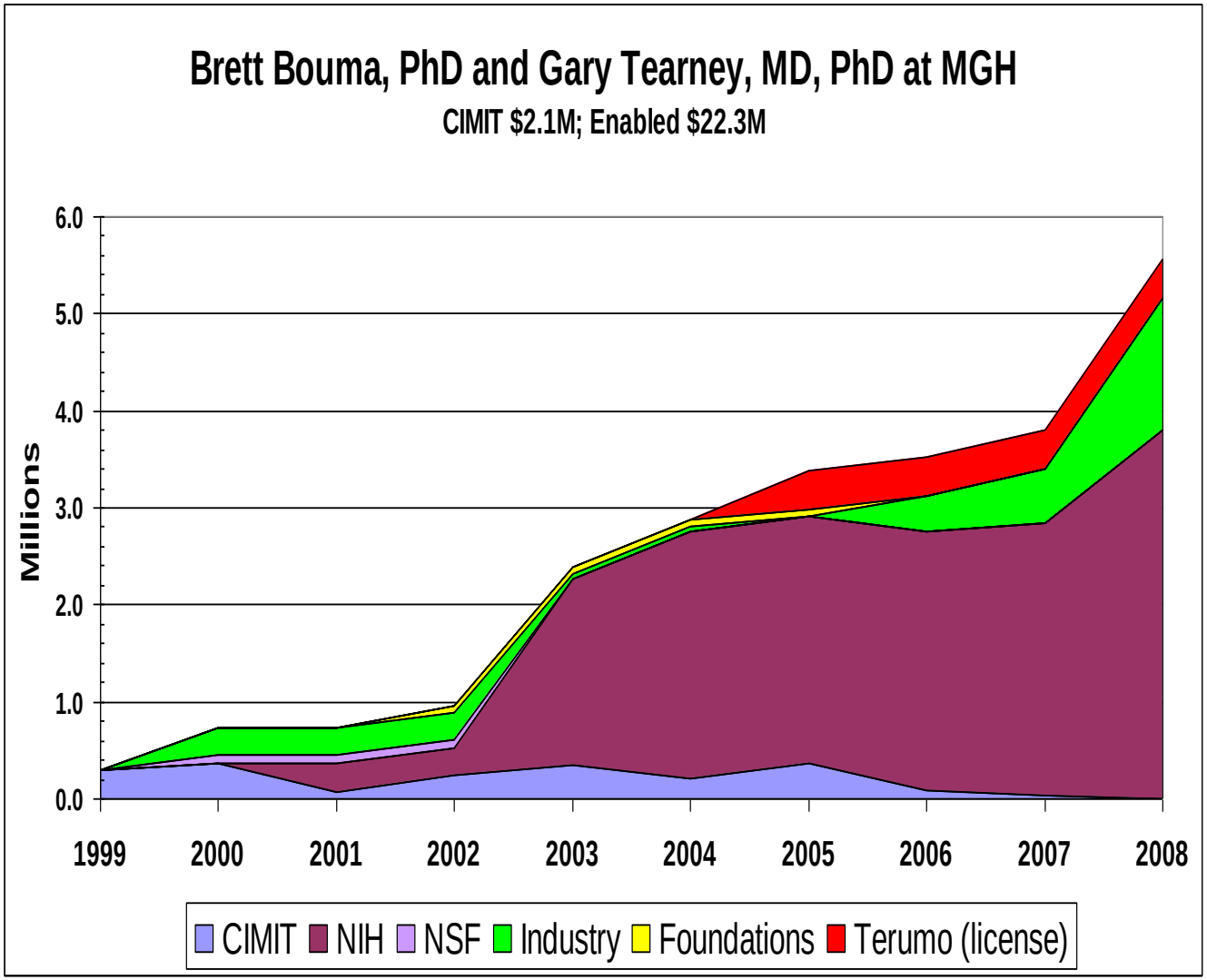
Key Factors in Success --
CIMIT Advanced Surgery Programs

- Longstanding commitment to clinical goals, safety, and procedure simulation at Mass General and partner institutions
- Multiple Drivers: Patient Safety, Care Efficiency, Initial and Operating Costs.
- Identification and focus on key quality issues
- Multi-site participation, including industry
- Open Source and Open Architecture technology base
- Sustained support of individual leaders.

IVOCT Translation Timeline



Meeting the Team Needs: Advanced Optical Coherence Tomography



Classic CIMIT Partnership: Mark Grinstaff and Yolanda Colson

Research and Care for TBI & PTSD

John A. Parrish, MD

- In the middle of the last decade, the US military and medical communities recognized the significance of Post Traumatic Stress Disorder (PTSD) and (Traumatic Brain Injury) in combat veterans.
- CIMIT has had two significant roles:
  - Supporting advanced research in TBI and PTSD
    - Now primarily directed and supported by the government
  - Developing new models for PTSD and TBI care based on local veterans and other healthcare systems
    - The Home Base program is a leading example of a national effort to implement hybrid systems which include the Veterans Administration (VA) and community hospitals.

Home Base Program

- Led by the Boston Red Sox Foundation and Massachusetts General Hospital, in cooperation with the VA.
- Founded in 2009; co-located with CIMIT.
- Mission: Lead regional and national efforts with a multi-disciplinary team of experts working together to help service members, Veterans and their families heal from TBI, PTSD and related conditions.
- Home Base is the largest private sector clinic in the US focused on this mission.

Care Model

- Home Base provides care to all Veterans and Families, regardless of ability to pay or discharge status.
- A “three generation” model of care is used to involve and include parents, children, and extended family members.
- The integrated team of child and adult physicians, nurses and nurse practitioners, physical medicine and rehabilitation specialists, licensed clinical social workers, and addiction specialists are supported by peer-to-peer outreach coordinators – all of whom are Veterans and/or Family Members of the Post-9/11 wars . Everyone works together to ensure that Veterans and their Families receive or are connected to appropriate and uniquely-tailored care.

Harvard Catalyst

- Established in 2008, Harvard Catalyst (The Harvard Clinical and Translational Science Center) is dedicated to improving human health by enabling collaboration and providing tools, training, and technologies to clinical and translational investigators
- Harvard Catalyst resources are made freely available to all Harvard faculty and trainees, regardless of institutional affiliation or academic degree.
- From 2008 to 2013, Harvard Catalyst was supported by a five-year, $117.5 million award from the National Center for Advancing Translational Science (NCATS) at NIH. A new Clinical and Translational Science (CTSA) award was made in 2013. Partner institutions have augmented these awards.
- This CTSA is part of a network of over 60 centers across the US dedicated to advancing C/T research.

Catalyst Approach

- "The key elements for success in clinical and translational research already exist at Harvard, including the intellectual force, technologies, and clinical expertise necessary to reduce the burden of human illness. What is missing is a systematic way for investigators from disparate disciplines and institutions to:
  - Find each other and form teams
  - Share tools and technologies
  - Receive advanced training and education in the principles and practice of clinical and translational science, and
  - Obtain seed funding to embark upon new areas of investigation"

Funding and Expert Support

- Harvard Catalyst offers pilot grants to Harvard investigators who need seed funds for early stage research anywhere along the translational spectrum, from basic/preclinical investigation to practice or population-based research
- Harvard Catalyst offers several expert advising services for clinical and translational investigators, ranging from general guidance on research design to consultations in areas like biomedical imaging and biostatistics.

Catalyst Offerings

Courses
Bioinformatics Workshops
Biostatistics Continuing Education
Certificate in Applied Biostatistics
Clinical Trial Design (CTD)
Comparative Effectiveness Research (CER)
Effectively Communicating Research
Fundamentals of Clinical and Translational Research (FaCToR)
Funding Your Research: Foundations and Philanthropy
Funding Your Research: NIH
Health Disparities Research Training and Events
Imaging Methods for Clinical and Translational Research
Introduction to 'Omics' Research
Introduction to Clinical Investigation
Introduction to Mixed Methods Research
Introduction to Translational Medicine
Leadership Strategies for the Researcher
Medical Device Development
Mentoring Program
Models of Disease (MoD) Boot Camp
Network Medicine
Regulatory Education and Events Series
Responsible Conduct of Research (RCR)
Successful Grant Writing Strategies (SGWS)
T3/T4 Research: Translating Effective Interventions into Practice
Understanding Biomarker Science: From Molecules to Images
ThinkResearch Podcast

Training Programs/Fellowships
Biomedical Informatics Master of Medical Sciences
Biostatistics Training
Clinical and Translational (C/T) Research Academy
Clinical Research Orientation Program for PhDs (CROPP)
Grant Review and Support Program
KL2/Catalyst Medical Research Investigator Training
Leder Human Biology & Translational Medicine
Mixed Methods Research Training Program for the Health Sciences

Educational Resources
Advanced Curriculum Compendium
Community Capacity Building Seminar Series
Education Video Library
IRB Visiting Program

Harvard Medical School Promotion Criteria

- Traditionally, faculty who pursued translational activities were not able to receive credit for that work toward promotions.
- New approaches were proposed and are now incorporated in the promotion criteria to provide translational investigators a specific promotion track.

B-BIC: Boston Biomedical Innovation Center

B-BIC

WE PROVIDE A ROAD MAP TO COMMERCIALIZATION

Joseph Loscalzo, MD,PhD Director

1 APPLICATION PROCESS
THE DEVELOPMENT OF A BUSINESS PLAN TO DETERMINE MARKET VIABILITY

2 WELCOME TO BBIC
GRANT FUNDING UP TO $350,000

3 PROJECT MANAGEMENT, SKILLS DEVELOPMENT & EXPERIENCED CONNECTIONS
EXPERTISE IN THE AREAS YOU NEED

4 REGULATORY STRATEGY
LEARN HOW TO PLAN AND PREPARE FOR REGULATORY APPROVALS

5 COMMERCIALIZATION SUPPORT
DEVELOPMENT AND FINANCING

6 EXIT BBIC

Boston Biomedical Innovation Center (B-BIC)

- B-BIC supports early stage devices, diagnostics, and therapeutic technologies that address unmet medical needs or offer great scientific opportunities with either immediate commercial potential or otherwise present compelling reasons for continued development. Program priority areas include: Cardiovascular Diseases, Lung Diseases and Sleep Disorders, Blood Diseases and Resources
- Running Rules
  - Faculty from the B-BIC member institutions are eligible to apply.
  - For-profit entities are eligible to apply as collaborators with Principal Investigators at member institutions.
  - The proposed work must support the advancement of technology that is owned by a B-BIC member institution.
  - B-BIC supports the advancement of technology towards commercial development. Funds are not awarded for the purchase of equipment, travel, or publication costs except under unusual circumstances.

Funding Programs

- **Pilot Awards** support projects to demonstrate proof of concept, such as prototype development, or reproducibility experiments in different model systems. Pilot awards provide up to $88,750 total cost. Pilot projects are expected to be completed within one year.
- **DRIVE Awards** are provided as investments in early-stage technologies that have the potential for commercial translation within two years. DRIVE awards provide up to $350,000 total cost to support proof-of-value studies.
- Indirect costs are provided at the applicant institution's negotiated Federal rate.

B-BIC Skills Development

- The Skills Development Center (SDC) offers open access online learning resources and customized services for funded investigators, all designed to promote academic technology commercialization efforts within B-BIC organizations and all Harvard-affiliated institutions.
- The SDC is a partnership between Boston Biomedical Innovation Center (B-BIC) and Harvard Catalyst.
- Activity Areas include:
  - Skill-Building Events
  - Videos
  - Resource Acquisition Support
  - Coaching
    - Presentations
    - Professional Development

Overall Summary
Some Elements of Success

- Keep score by making the patients healthier, or enabling the system to care for them more effectively.
- Establish a culture and keep it evergreen.
- Fund only projects of exemplary quality
- Help people who wish to work in the translational space build their careers.
- Share the secret sauces with others.
- Cheerlead, particularly for teams that collaborate effectively across boundaries.
- Remember who is paying for this work and be sure they are glad they are.

The End