

CIMIT[®]

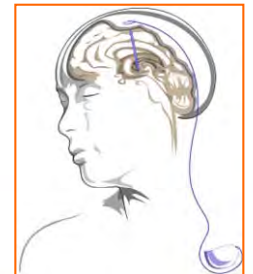
Center for Integration of Medicine
& Innovative Technology

A Decade's Experience with One Model for Advancing Healthcare Through Innovative Technology

Presented to:

ADL Alumni Association

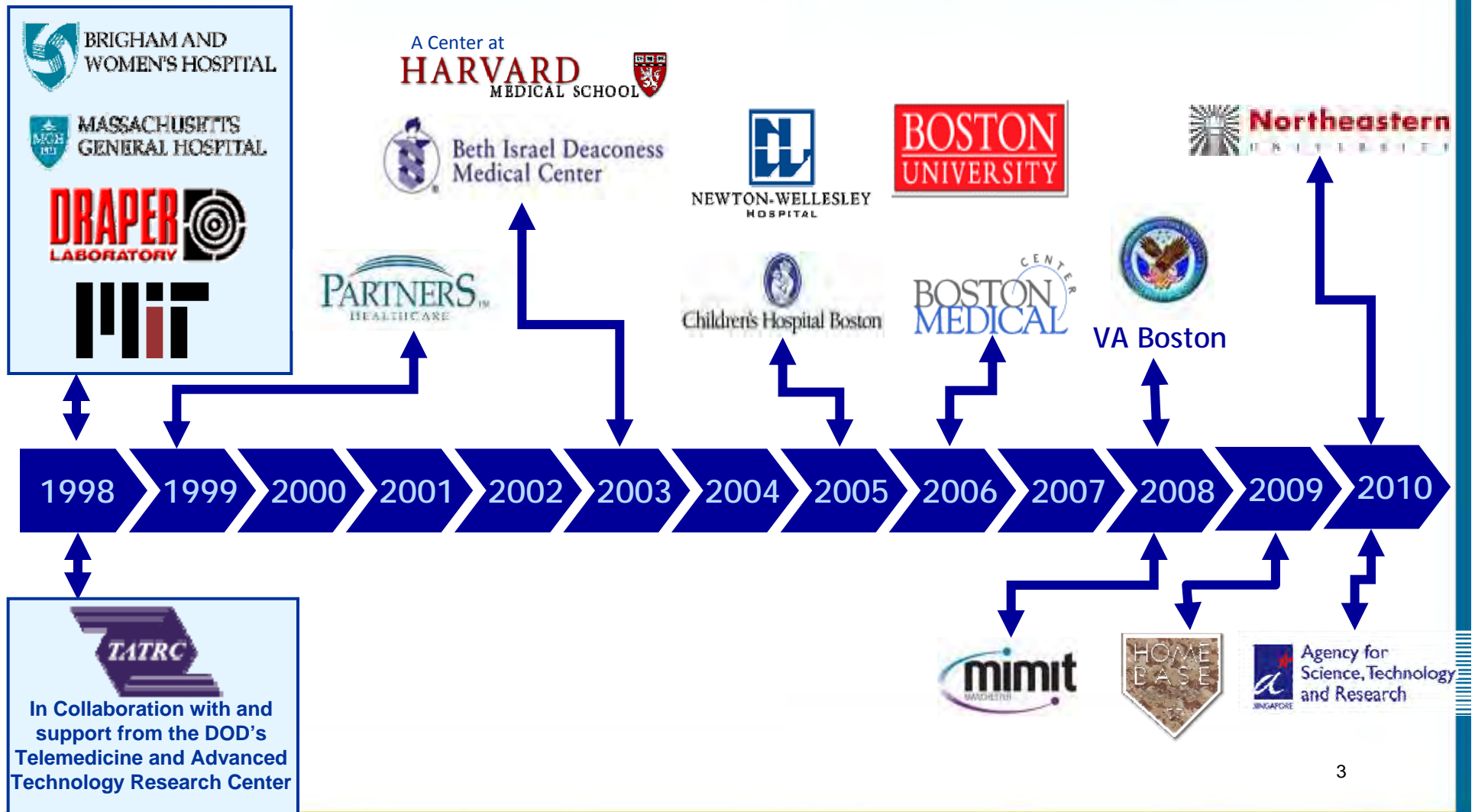
November 17th, 2010



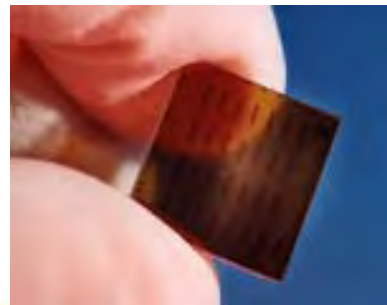
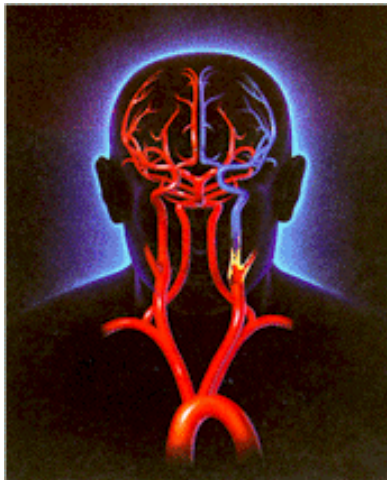
Agenda

Time	Topic
10 Min.	CIMIT Overview
10 Min.	Clinical Impact Study
10 Min.	CIMIT Strategic Initiatives
30 Min.	Discussion

CIMIT: A growing, voluntary, formal consortium among 13 Boston institutions with other world-class organizations



CIMIT: Mission and Focus



CIMIT Mission

To improve patient care by facilitating collaboration among scientists, engineers and clinicians to catalyze the discovery, development and implementation of innovative technologies.

CIMIT Domain

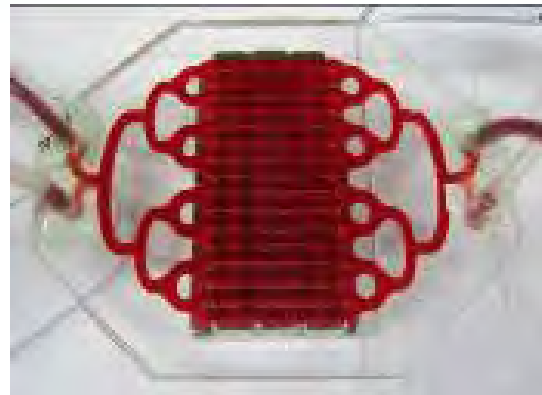
- *Devices*
- *Procedures*
- *Clinical Systems*

Project Examples ... (6 of more than 500)

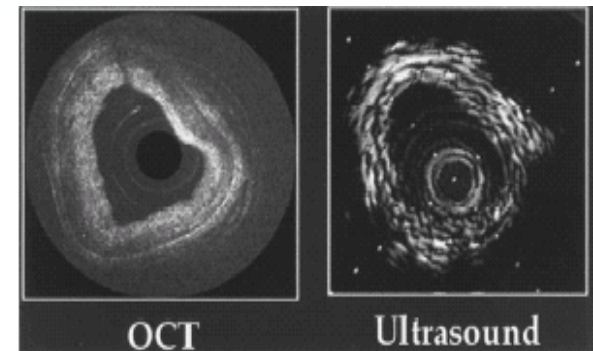
Operating Room of the Future



Microfluidic Blood Filter for Sepsis



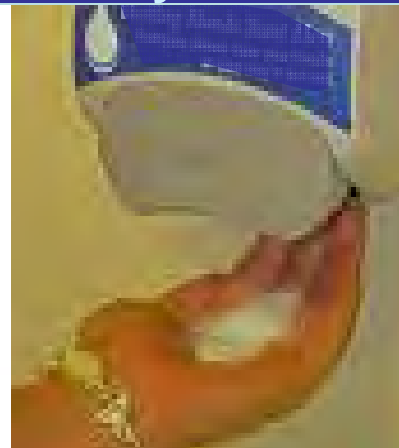
Optical Diagnostics



Trauma Mannequin



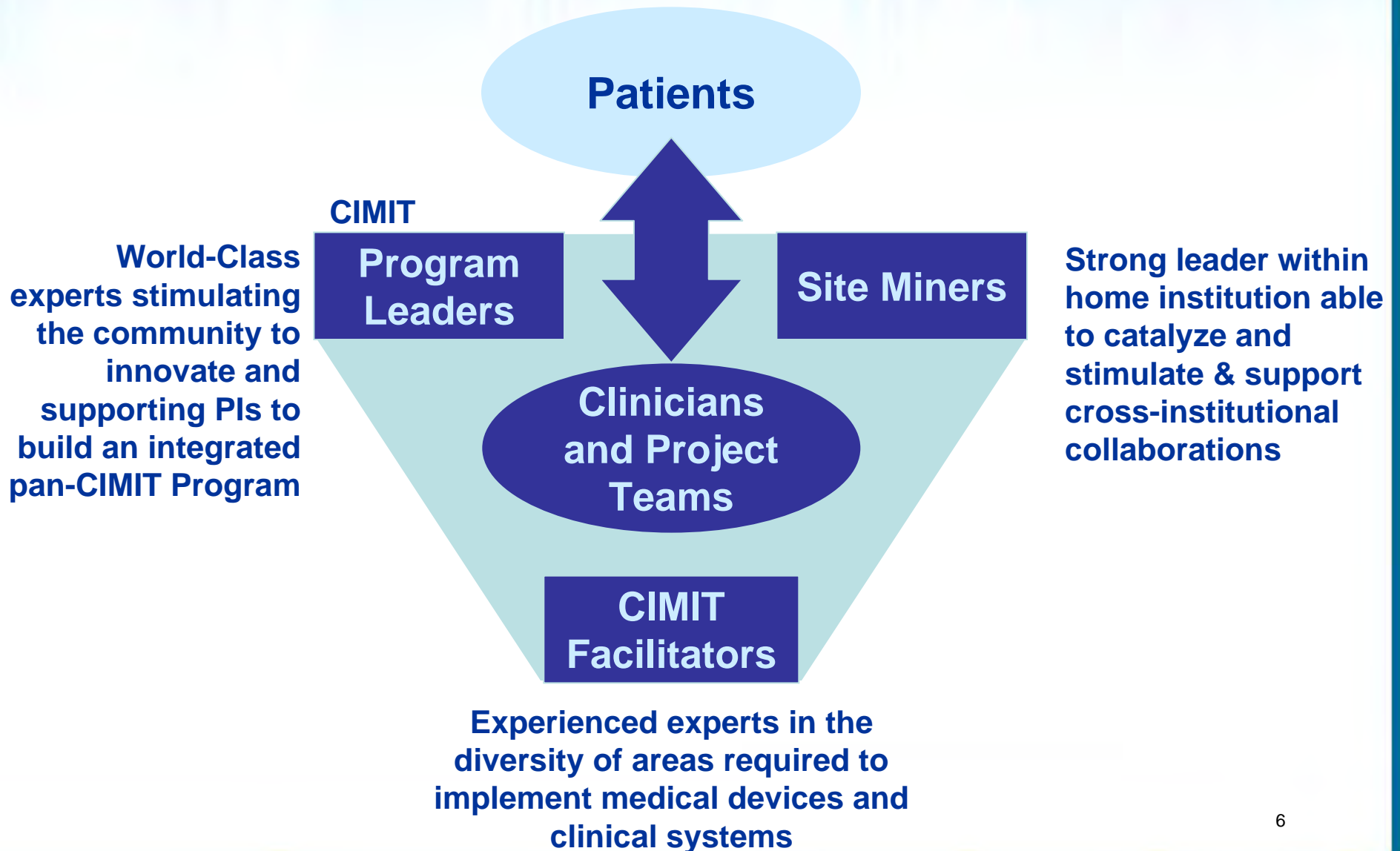
Hand Hygiene System



Seizure Detection



People: A diverse mix focused on impacting patient care



CIMIT Process: The 3F's

Finding

- Site Miners
- Program Leaders
- CIMIT Forums
- Conferences
- Courses
- Request for Proposals
- Growing profile



Funding

- Competitive seed funding for early, high-risk, collaborations
- \$100K - \$200K/yr per team
- 50 new teams/yr

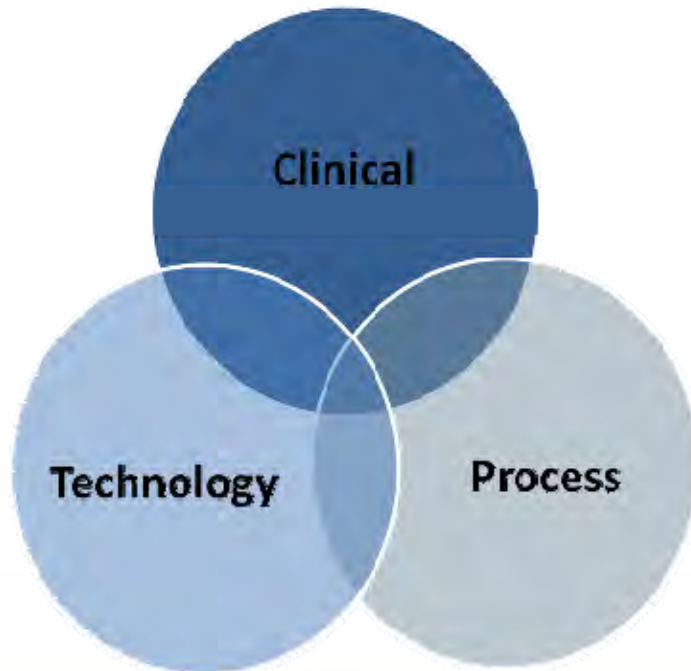
Facilitating

- Finding collaborators & supporting proposals
- Understanding and Protecting IP
- Developing commercialization options and plans
- Ensuring compliance
- Anticipating and addressing regulatory issues
- Finding & acquiring additional funding₇

CIMIT Programs: Clusters of projects & content experts coordinated by Program Leaders.

Programs are Launched by:

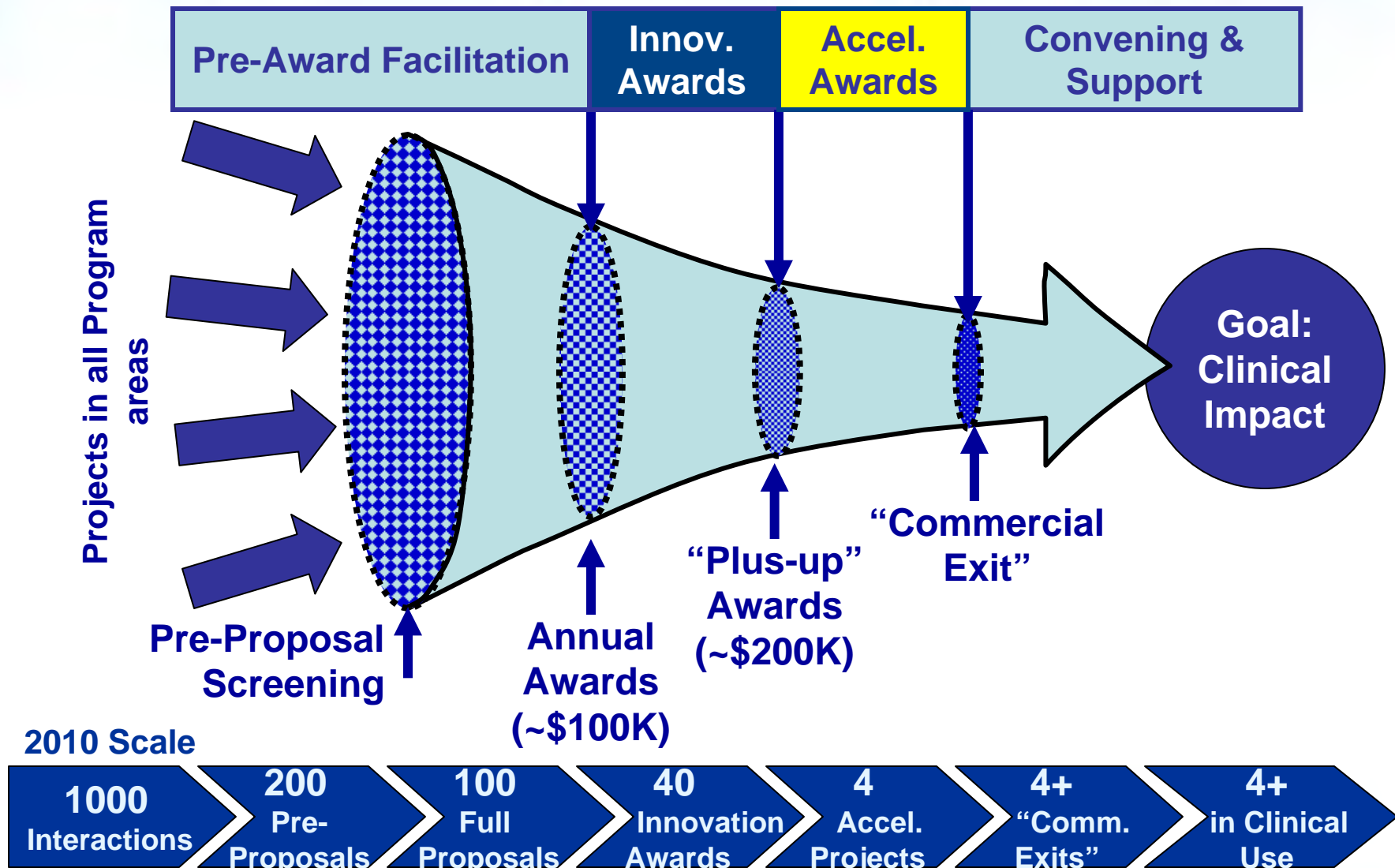
- Strategic priority/clinical need
- Committed champion
- Clustering of projects/proposal
- External need/funding



Current CIMIT Programs

- Biodetection & Sepsis
- Biomaterials & Tissue Engineering
- Cardiovascular Disease
- Clinical Systems Integration
- Global Health Initiative
- Inhalation Technology
- Minimally Invasive Surgery
- Neurotechnology
- Optical Diagnostics
- Trauma & Casualty Care
- Traumatic Brain Injury
- Post Traumatic Stress Disorder⁸

The CIMIT Award Model: Supporting clinician-led teams.



Some Recent Successes...

Inter-operability

- \$10 Million NIH Quantum Grant Awarded to Interoperability Team Led by Dr. Julian Goldman



Hand Hygiene Compliance

- First Accelerator project and JIF Award
- License Term Sheet with NewCo (HanGenix) executed
- A*STAR co-investment and installation at two Singapore hospitals



Trauma Patient Simulator (COMETS)

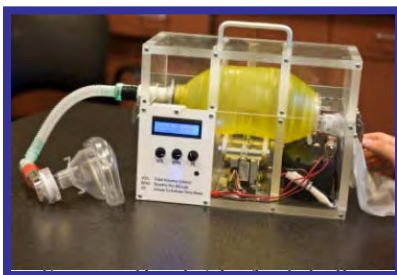
- License agreement executed, product release expected this year
- Leading international simulation company expanding its medical business



Some Recent Successes...

Low Cost Portable Ventilator

- A team of MIT students, guided by a BU/VA clinician designed a system using a widely available manual pump
- Low cost portable ventilator could be lifesaver for people in remote locations and for mass casualty response
- Recently received \$100K Gates Foundation Award



Non-surgical Repair of ACL Injury

- Stimulate natural ACL injury repair with injection of collagen gel and platelet-rich plasma to regenerate tissue
- Comparable to strength of traditional reconstruction in animal studies
- Utilized a MIT student project, formed venture-backed new company this year:



MGH APF

- Ambulatory Practice of the Future opened in July 2010
- New innovative patient-centered practice providing care “in the right place - at the right time”
- Living innovation laboratory
- Redesigned physical space and virtual practice



Some Ongoing Initiatives ...

Social Media Tools

- CIMIT has established a relationship with a software company (Induct) to implement an “Open Innovation” model
- Initial functionality:
 - CIMIT Connector to find collaborators (semantic search)
 - Project Collaboration space
 - Workgroups (private)
 - Discussion groups (public)
 - Needs and opportunity logging
 - Proposal management

CIMIT Innovation Workshop

- First workshop– conducted interspersed with CIMIT Innovation Congresses
- Topic: **Early, Innovative Resuscitation and Bleeding Control After Injury**
- George Velmahos (Trauma Program Lead)
- Oversubscribed!



Clinical Impact Study

- After 12 years, time to measure the impact of CIMIT Model
- Goal is to measure:
 - Efficiency of grant funds
 - Impact of facilitation
- CIMIT’s collection of insights and information hold insights that can help improve the model
- Establish approach for ongoing monitoring and benchmarking

Lessons and Experiences:

- **Site Miners = great investment**
- **User inspired innovation is powerful and fragile.**
 - “Clinical Pull” more effective than “Technology Push”
 - Junior faculty a great source of innovation
- **Supporting “Individualized” collaboration is essential**
 - Making connections requires a variety of “convening” vehicles.
 - Facilitation must be very pro-active (busy clinicians don’t have time or expertise to prototype or demonstrate feasibility of innovations.)
- **Building communities of interest (Programs) and connecting projects improves results**
- **Interfacing with “implementation” partners needs to start early**

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Clinical Impact Study (CIS) ...

Premise

- After 12 years, time to measure the impact of the CIMIT Model
- CIMIT's collection of information holds insights that can help improve the model

Situation

- In the past academic metrics reported
- A desire to measure "Clinical Impact" and
 - Efficiency of grant funds
 - Impact of facilitation
- Yet "Clinical Impact" has not been easy to define or measure!

Goals

- Quantify the portfolio:
 - Inputs: resources applied
 - Outputs: impact of projects
- Identify correlations and extract lessons learned to:
 - Share with others
 - Further improve CIMIT Model
- A shared method⁶ and benchmark with

Study Methodology: Projects initiated from '98 to '06

1. Data Acquisition and Assembly

- Assembly of available data and reports (quarterly, annual, etc.)
- Summary of projects and results by CIMIT Staff
- PI self-evaluation surveys of results and roadblocks (e.g. Human or Animal Studies Approval, Funding, IP, etc.) and follow-up interviews by CIMIT Staff
- Review and assessment of assembled data by Program Leaders and Site Miners.
- Review and summation by CIMIT Staff

2. Quantification of Objective and Qualitative Data

- Clustering of projects for quantification
 - The 261 projects were reduced to 117 projects & clusters to evaluate
- Quantify inputs; Funding, Facilitation, Key Connections, etc.
- Quantify outcomes; Clinical Impact, Patents, Publications, etc.

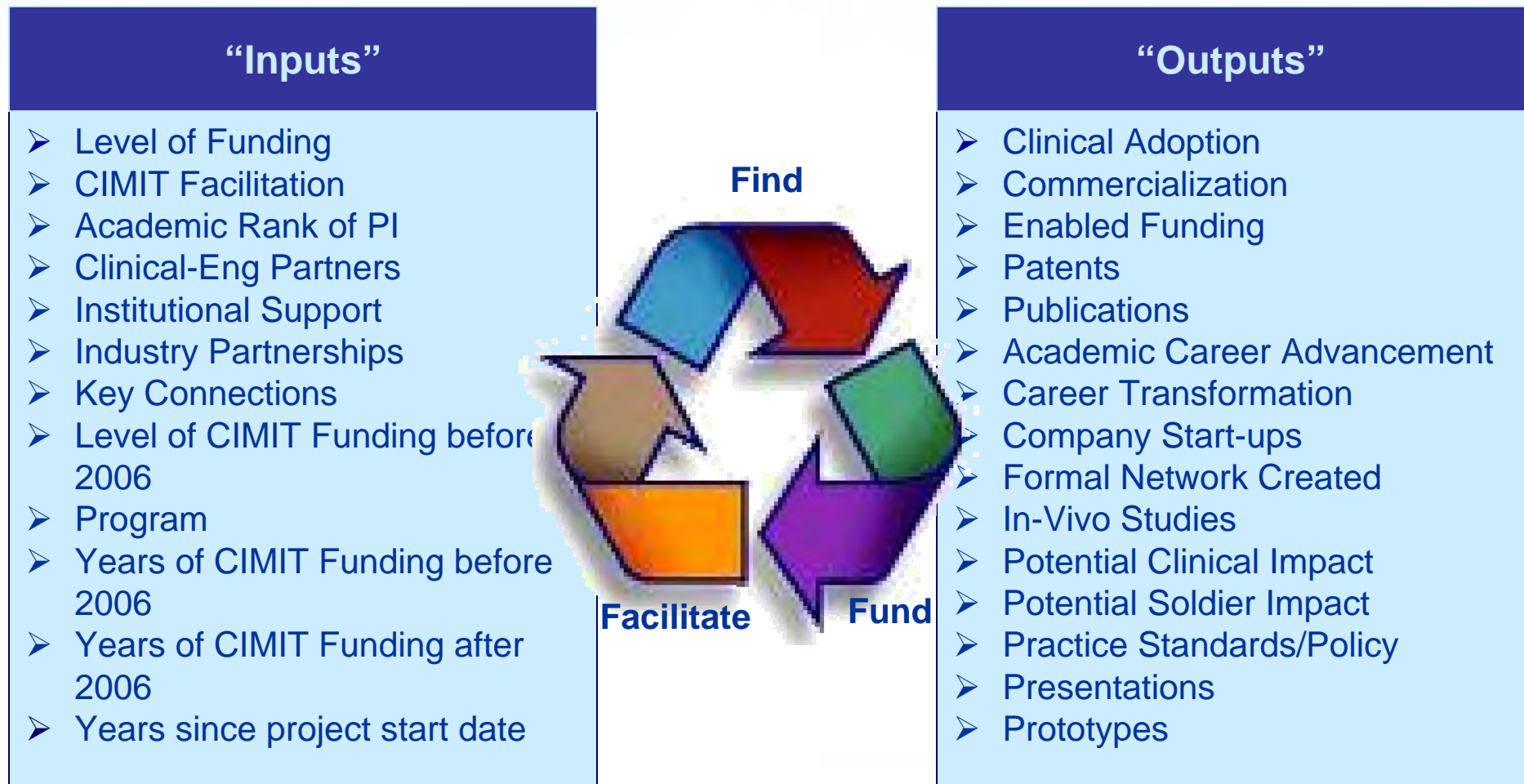
3. Statistical Analysis

- Screen data for robustness
- Search for significant correlations of outcomes and inputs
- Examine correlations to identify local optimums (CIMIT “Sweet Spots”)

4. Summarize Lessons Learned

- “Story telling” examples
- Prose summary
- Presentation style summary

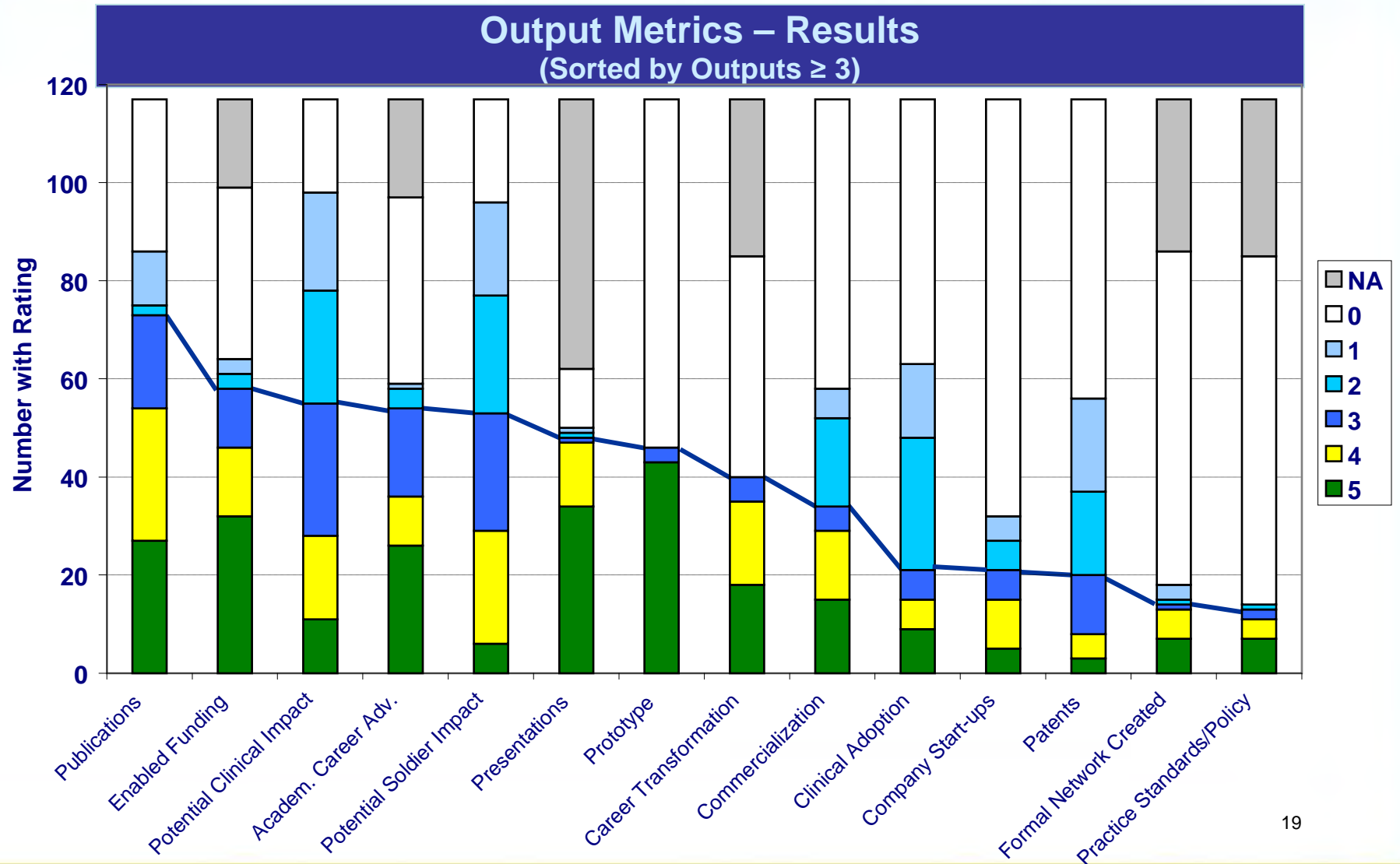
The following are the Input and Output metrics studied and quantified:



The Inputs and Outputs were each “quantified” along a 0 to 5 scale to enable statistical analysis.

Example Metrics		Score				
		1	2	3	4	5
Inputs	Academic Rank	Fellow or post-doc	Instructor	Assistant Professor	Associate Professor	Professor
	CIMIT Facilitation	Start-up facilitation	Episodic support from single resource	Episodic support from multiple resources	Ongoing, dedicated CIMIT support from single resource	Ongoing, dedicated support, multiple resources
Outputs	Clinical Adoption	Procedure of IDE clinical trial planned	Procedure or IDE clinical trial completed	Regulatory approval for human use	In clinical use	Standard of care
	Commercialization	Device proof of principle; pre-licensing studies	Discussions with companies for license or with funders	Licensing agreement with company or NewCo	Technology under commercial development	Regulatory approval and sales
	Patents	Disclosures or patent applic. under devel	At least 1 patent filed	1 Patent awarded	2 to 5 patents awarded	Over 5 patents awarded
	Potential Soldier Impact	Low potential to impact a low # of soldiers	Mod potential to impact a low to med # of soldiers	Mod potential impact a medium to high # of soldiers	High potential To impact a low to med # of soldiers	High potential to impact a med to high # of soldiers

The results show a high fraction of projects create output in one form or another:



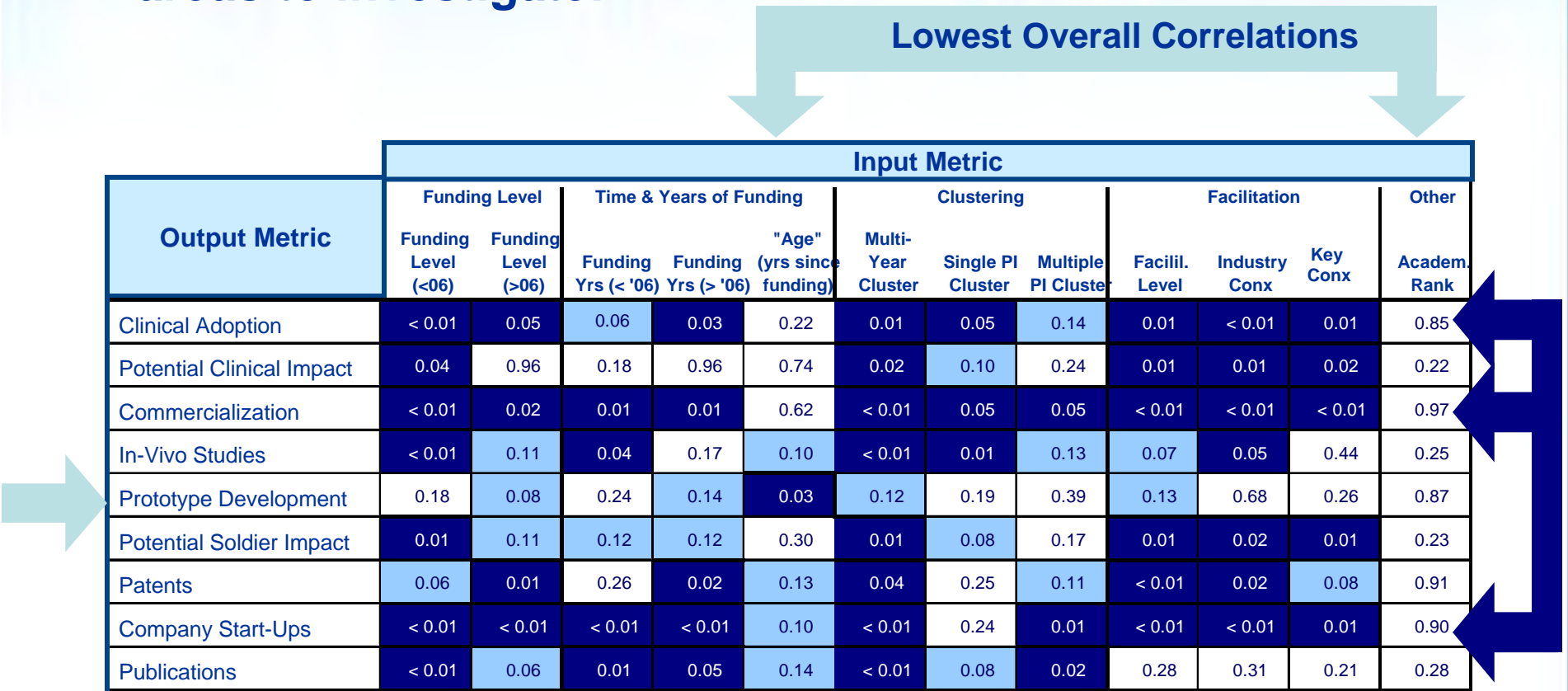
A snapshot in 2009 of output metrics from 261 projects in 117 clusters initiated from '98 to '06

- **Clinical Adoption:** >20% with regulatory approval for human use.
- **Commercialization:** > 30% with a licensing agreement
 - 20+ NewCos
 - 10+ License agreements
- **Enabled Funding:** > 60% with some follow-on funding, the totals:

Direct to Investigators	~ 3 times CIMIT funding to PIs
+ Commercial Inv	~ 6 times CIMIT funding to PIs
<hr/>	
= Total	>~9 times CIMIT funding to PIs)
- **Patents:** > 15% of with at least one issued patent (a total of over 30)
- **Publications:** > 60% with at least one peer reviewed article (a total of over 700)

Note: The percentages corresponded to a "3" rating for each output metric

Correlations between inputs and outputs show several areas to investigate:



Interpretation:
Cell is probabilistic outcome of likelihood ratio test

- Significant** (Dark Blue)
- Marginal** (Light Blue)
- Little/Low** (White)

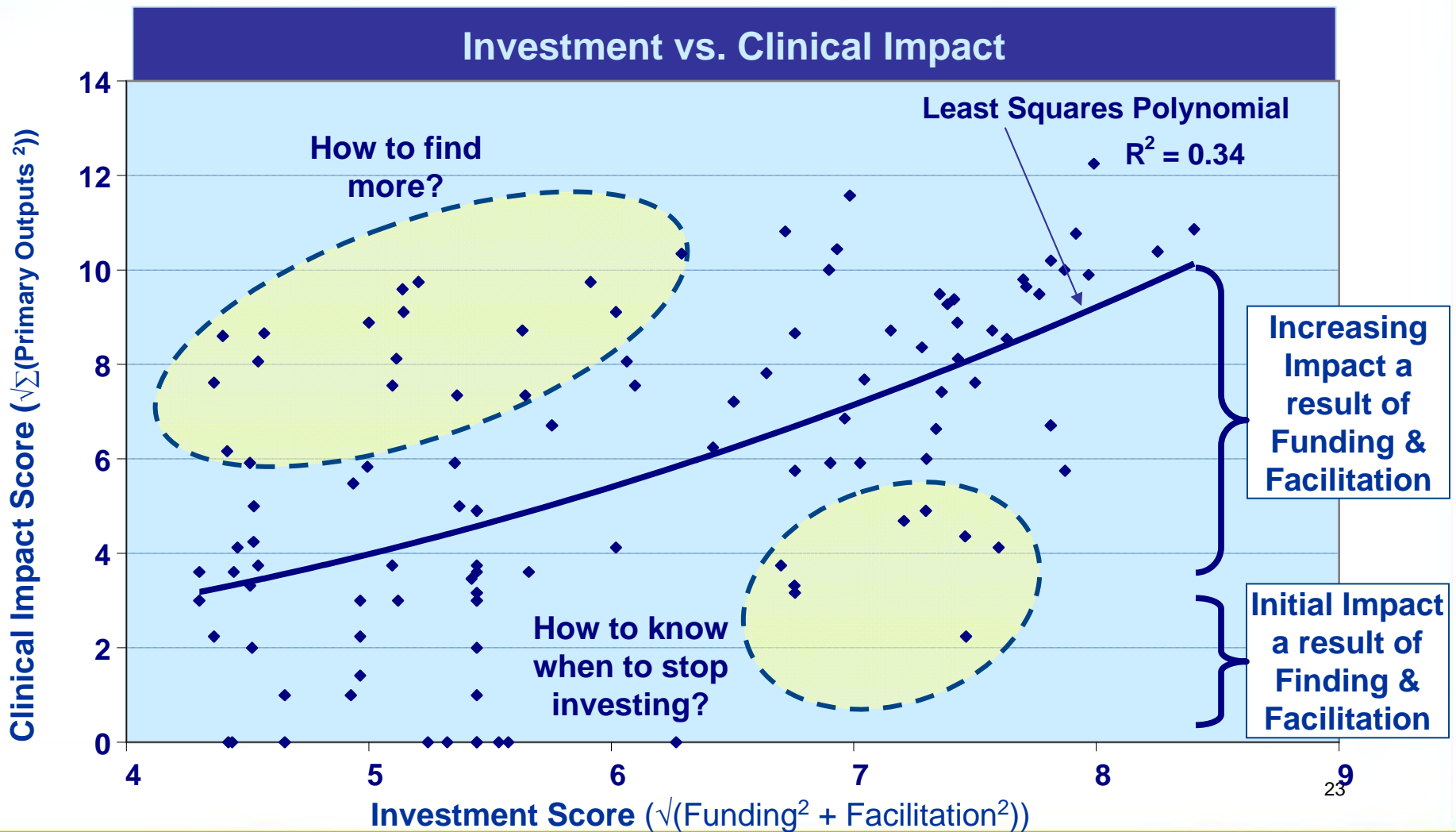
Highest Overall Correlations

Consolidated input (“Investment Score”) and output (“Clinical Impact Score”) metrics were defined to help analyze the data

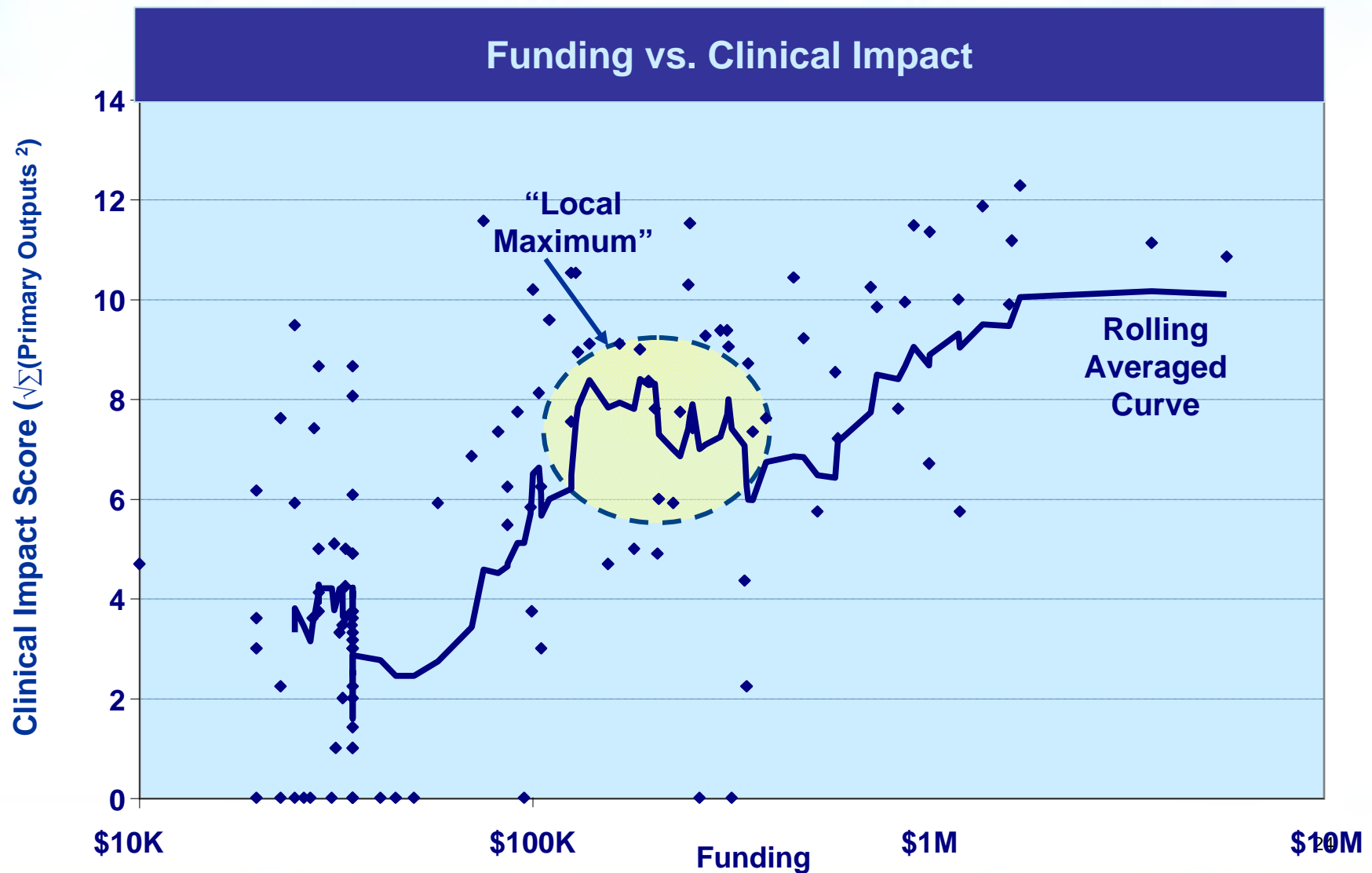
- Investment Score = $\sqrt{(\text{Funding}^2 + \text{Facilitation}^2)}$
 - Funding: Cash awards to Investigators
 - Facilitation: Level of support provided to investigators

- Clinical Impact Score = $\sqrt{\sum \text{Primary Outputs}^2}$
 - Clinical Adoption: Ultimate goal of impacting patients (warriors, their families and civilians)
 - Commercialization: Intermediate goal of making products available and scaling impact
 - Enabled Funding: Intermediate goal of finding others to advance the technology beyond CIMIT’s means
 - Patents: Intermediate goal of demonstrable novelty and investment
 - Publications: Long term goal of disseminating information
 - Academic Career Advancement: Long term goal of encouraging more focus on translational research and implementation

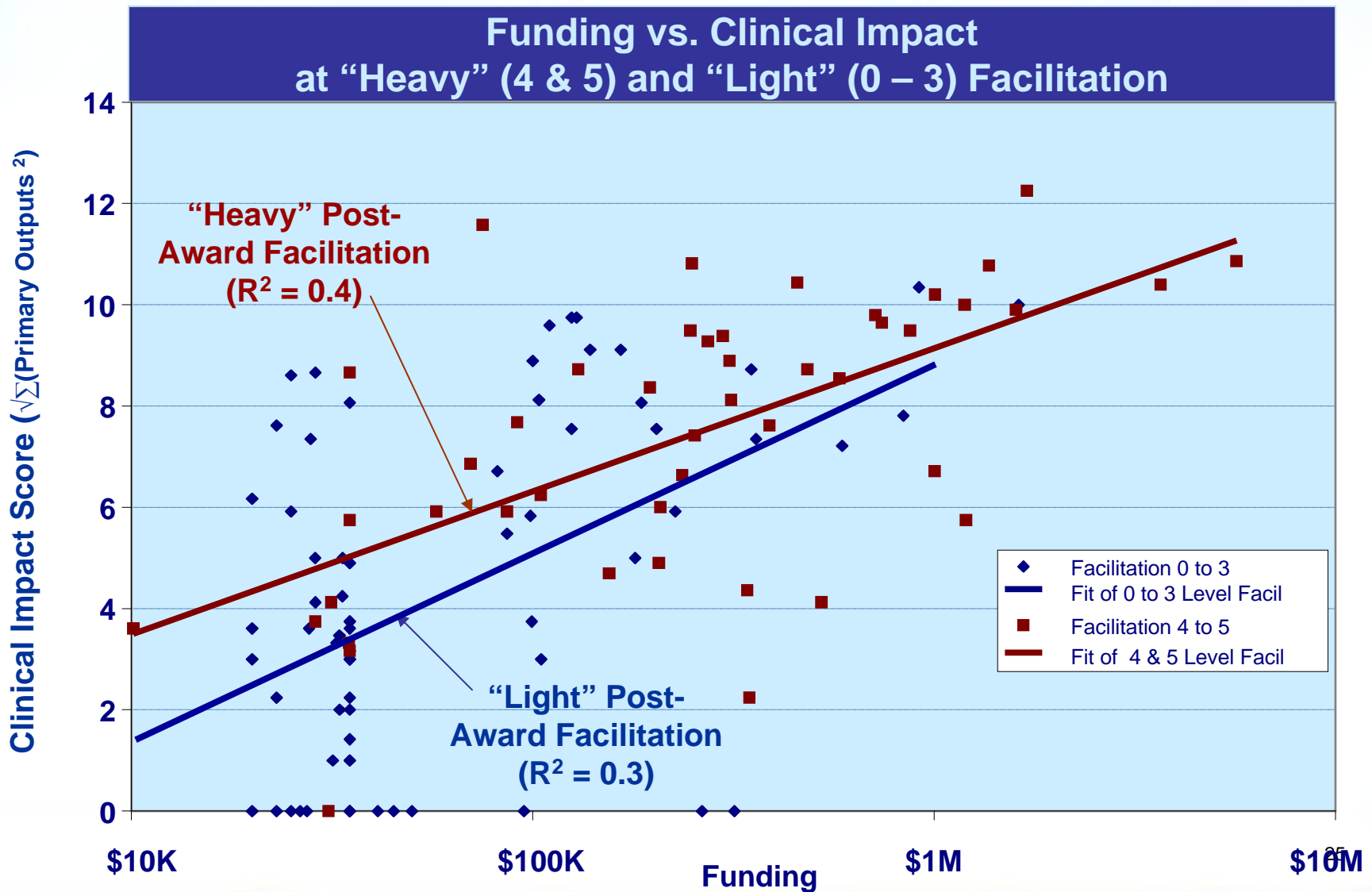
Results show that “Clinical Impact” starts high and increases with the “Investment”, with areas to study:



The results also show the impact of funding increases with amount, but peaks in the \$200K range (+/- \$100K)



CIMIT's post-award heavy Facilitation appears to be of highest total value in the funding mid-range.



Learning from the Clinical Impact Study...

- The clinical impact study identified correlations between:
 - Independent “input” variables that CIMIT controlled
 - Dependent “output” variables that resulted from the process
- Correlations by themselves do not prove cause and effect:
 - The CIS correlations identify relationships for examination
 - “Story telling” of individual cases is needed to understand any causal nature of relationships
- The correlations do highlight potential CIMIT “Sweet Spots”:
 - What has worked for CIMIT (not why...)
 - The underlying stories illustrate the unique advantages made possible by CIMIT’s situation, structure and strategy.
 - The deep-dive “Story Telling” allows us to extract apparent causality and compelling lessons.

CIMIT Model: Learning from the Clinical Impact Study

- **Cost Effectiveness**: CIMIT's greatest "bang-for-the buck" occurred in projects with funding in the \$100K to \$300K range.
- **"Gardens"**: Projects conducted as part of a "cluster" of activities are more effective than those done in isolation.
 - Thematic areas
 - Serial projects (gated decisions over time)
- **"New Investigators"**: Junior faculty were as successful as more senior investigators working within the CIMIT model.
- **"Speed"**: Time alone is not correlated with clinical impact, with early indications of potential success.
- **"Facilitation"**: Targeted and skilled facilitation is powerful at any stage of the innovation cycle, from the pre-proposal phase onward.

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CIMIT's Strategic Initiatives: Leveraging experiences and the network

Formalized "Accelerator"

- Invest both:
 - Funding (\$100K to \$300K)
 - "Heavy" facilitation support
- Speed time to a commercial exit or implementation

Neuro Health

- Leveraging the synergies between:
 - Neurotech
 - TBI and Neurotrauma
 - Post Traumatic Stress Disorder
 - Pain Management
- Research arm of the MGH – Red Sox Foundation clinical Home Base Program

Integrated Clinical Environments

- Enabling patient-centered care by de-fragmenting care within and across settings.
- Utilize strength in:
 - Novel devices
 - Interoperability
 - "Living Labs"
 - Simulation & decision support systems.

CIMIT Accelerator Overview

➤ Objective:

- Find, fund and facilitate projects that have a realistic chance of a clean handoff to industry or widespread clinical adoption within 12-18 months.
- Become a financial self-sustaining activity

➤ Accelerator Candidates:

- Invited to participate
- Project or PI previously funded by CIMIT
- PI must be eager to work very intimately with the accelerator team:
 - Accepting of “heavy facilitation”
 - “Project Champion” (who need not be the PI)
 - CIMIT Facilitators and outside experts
- Get to an “exit” with ~\$200K of direct funding
- The team must complete an **Impact Plan**



A Home Base for Veterans and Their Families



**RED SOX
FOUNDATION**



**MASSACHUSETTS
GENERAL HOSPITAL**

Home Base Mission

The Red Sox Foundation and Massachusetts General Hospital Home Base Program serves New England by identifying, motivating, and treating veterans and families impacted by the invisible wounds of war.

The Home Base Program serves the nation as:

- **A model of a fully integrated comprehensive program**
 - Patient Care**
 - Family Support**
 - Education**
 - Research**
 - Vet-to-Vet Outreach**
- **A successful model for private-public collaboration**
- **A source of new communication and education capabilities**
- **A leader in finding and implementing new treatments for warriors and family members affected by post traumatic stress disorder (PTSD) and traumatic brain injury (TBI)**

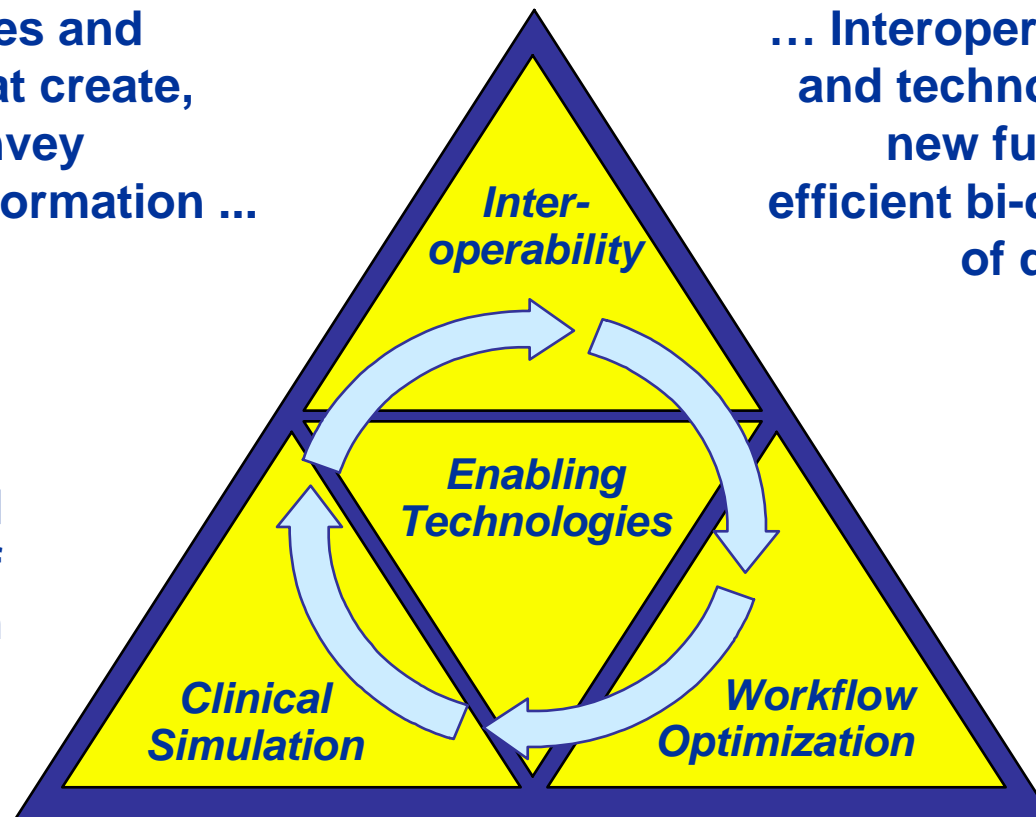
Integrated Clinical Environment (ICE) Overview:

CIMIT ICE Elements

Novel devices and methods that create, use and convey available information ...

... Interoperable standards and technology, enabling new functionality and efficient bi-directional flow of data to EMRs ...

... Exploration, testing and validation of complex system solutions ...



... Systems engineering to optimize workflows and information availability for clinicians.

Coordinated to ensure continuous, accelerated improvement and learning.

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