

CIMIT:

A growing network of world-class institutions and regional clusters fostering collaboration among clinicians, technologists and entrepreneurs to stimulate and accelerate innovations into patient care while creating regional economic growth through start-ups and licensing relationships.

Boston Consortium Institutions

- Beth Israel Deaconess Medical Center
- Boston Medical Center
- Boston University
- Brigham & Women's Hospital*
- Children's Hospital Boston
- Draper Laboratory*
- Harvard Medical School
- Massachusetts General Hospital*
- Massachusetts Institute of Technology*
- Northeastern University
- Newton-Wellesley Hospital
- Partners HealthCare
- VA Boston Healthcare System

*Founding Institutions

Affiliates:

- Manchester, UK
- NHS England
- A*STAR - Singapore
- NIBIB - POCTRN
- M+ Vision
- NEPDC
- NHLBI NCA - B-BIC
- CAMTech

Strategic Support:



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Introduction:

This is an ongoing, work-in-process update of CIMIT's Clinical Impact Study (CIS). First conducted in 2009, the CIS is a self-assessment by CIMIT faculty and investigators of its project portfolio and Accelerator Program and now includes projects initiated between 1998 and 2012. The innovation portfolio, an important subset of the ways in which CIMIT helps speed innovations into patient care, represents an investment of almost \$70M over 14 years. It also represents a rather unique longitudinal set of experiences from which to learn.

The goal of the CIS is to understand and learn from CIMIT's experience with finding, funding and facilitating projects to improve the support it provides to investigators in advancing innovations into patient care and to be able to share the lessons learned with others. CIMIT initiated the CIS in part because very little had been published regarding translational research metrics – which remains the case today. CIMIT considers innovation in healthcare to be a codify-able, learnable process, and as such sees metrics as being critical in being able to optimize the efficiency and effectiveness of the processes that CIMIT invests in healthcare innovations and their teams.

While we have not found a source of comparative data to be able to benchmark CIMIT's results, the results show significant evidence that the CIMIT Model of Healthcare Innovation generates an enviable success rate, particularly with early stage projects and investigators new to innovation. We have been able to use the data to benchmark CIMIT's own internal initiatives to understand where CIMIT is most successful and therefore where it can best concentrate its efforts.

Background and Motivation:

CIMIT started as a consortium of greater Boston's premier clinical, research and academic institutions. It has since grown into a network of affiliates across the US and abroad. Its mission is to accelerate the use of technology to improve patient care by facilitating collaboration among clinicians, technologists and entrepreneurs, along with the ecosystem of companies, federal and state government bodies, etc. Its goal is to address important unmet clinical needs by rapidly developing and implementing innovative products, services and procedures/workflows.

CIMIT developed and, over the years, refined a suite of input and output metrics that attempts to capture leading and lagging indicators of its success. The suite is a mix of traditional academic, commercial and clinical metrics. It is important to stress that the metrics any organization chooses should be those that are targeted by its mission. In CIMIT's case, clinical impact anywhere is of highest priority, hence the focus of this work.

The 2014 CIS Portfolio

In total, CIMIT invested just over \$69 million in 585 discrete projects initiated between 1998 and 2012. Each discrete project was peer reviewed and selected through a competitive process. Many of these discrete projects intertwine in creating a solution to an unmet healthcare need. In such cases, the input of several projects merged into a single "solution" captured by a single set of output metrics.

CIMIT is now capturing metrics on a real-time basis and uses information from investigators as much as possible. However, since we did not start the process until 2009, we have not been able to get reliable data on several of the projects CIMIT had supported many years before. The CIS portfolio of projects for which we have data includes 73% of the total number of CIMIT-funded projects (428 of 585) reflecting 80% of the total amount of CIMIT funding (\$55M of \$69M).

Metrics:

Table 1 below present the input and output metrics collected in this 2014 CIS. The metrics include numerical values where possible, such as funding amount, number of patents, etc. For other metrics, we found that scales were often more appropriate, particularly for certain types of innovations. For workflow projects such as the CIMIT-supported “Operating Room of the Future”, which are disseminated by way of publications and meetings to many institutions across the country, it has often proven very difficult to accurately assess the number of patients that have been impacted. As a result, it is near impossible to generate a single number with any accuracy, but using a scale can provide an estimated range. In addition, we used self-ratings for career impact, as no objective standard measures are available.

Table 1: 2014 CIS Input and Output Metrics

Input Metrics	Output (Tracking) Metrics
1. Project Characterization: <ul style="list-style-type: none"> Institution Source(s) Program Area and Project Description 2. Investigators: <ul style="list-style-type: none"> Seniority of PI (1-5 scale) Collaborators (number and type) 3. Prior & Concurrent Support: <ul style="list-style-type: none"> Prior funding (total \$s) Other support (descriptive) 4. CIMIT Support: <ul style="list-style-type: none"> Funding (total \$s) Facilitation (1-5 scale) Start Year and Duration Type of Award 	1. Clinical: <ul style="list-style-type: none"> Number of Patients Impacted (1-8 scale) Technology Readiness Level (1-10 scale) 2. Academic: <ul style="list-style-type: none"> Follow-on funding within Academia (Σ\$s) <i>Recognition (PI and Team, 1-5 scale)</i> Career Impact (1-5 scale) Peer reviewed publications (number) <i>Presentations (number)</i> 3. Commercial: <ul style="list-style-type: none"> Capital invested (Σ\$s) IP (number of disclosures, patent applications and granted patents) <i>Revenue/Jobs Created or Cost Saved</i>

Note: Descriptions, comments and feedback were solicited on all of the above fields; see appendix for definitions of scales. *Italics* indicates some difficulty due to inconsistent responses.

Sample Results-to-Date:

This section highlights some interesting results, with the full report being prepared. The following tables and charts below present some representative outputs and the discussion outline some preliminary insights.

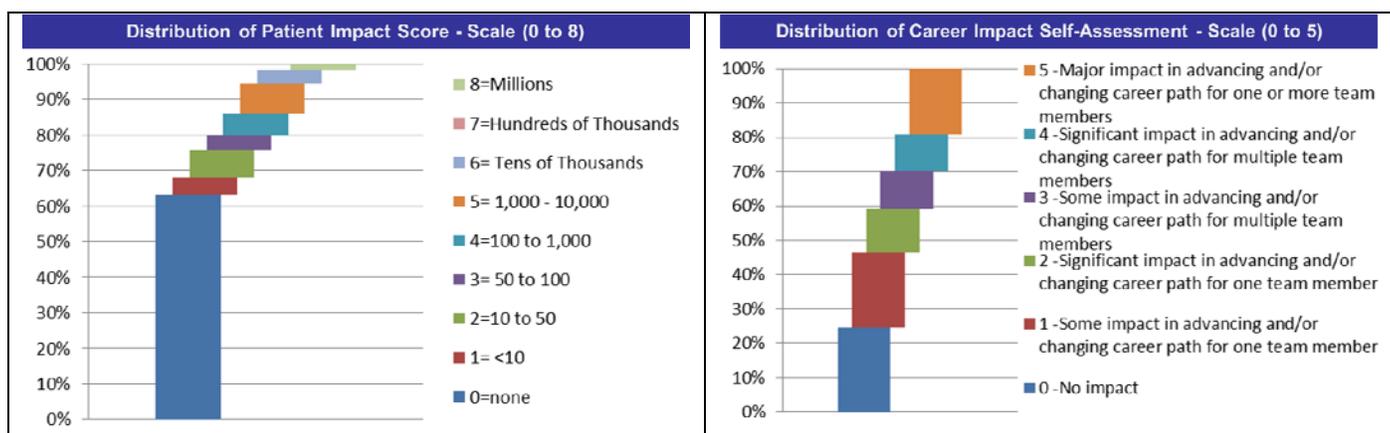
Table 2: Fraction of solutions that have reached a CIMIT defined milestone:

Portfolio Output Profile	%	Notes
Still Active	70%	CIMIT plays an important role in initiating projects, so a high number is very important
Received Follow-on Funding	49%	About 1/2 are able to get follow-on investment - if this number is too high we are not taking enough risk
Touched Patients (Score >=0)	37%	A high number likely due to the "clinical pull" approach
Made a significant or major impact on one or more team members' career	30%	An important long-term metric that demonstrates CIMIT's ability to influence careers and improve the ecosystem
Reached Commercialization	27%	A very high number given the early stage at CIMIT starts - defined as having moved into a company
Approved for Clinical Use (TRL>= 6)	17%	A lagging indicator that is likely to grow over time as projects mature and get approval

Table 3: Amplification of the monies that CIMIT invests in projects:

Sample Output Metrics	Survey Data	Ratios
Follow-on Funding	\$516M	9.4 - Follow-on \$\$/CIMIT \$\$
Commercial Investment	\$597M	11 - Comm Invest \$\$/CIMIT \$\$
Total Enabled Funding	\$1,113M	20 - Total Follow-on and Comm'l
Peer Reviewed Publications	2,293	42 - Pubs/\$M CIMIT Funding
Issued US Patents	458	8.3 - Patents/ \$M CIMIT Funding

Charts 1 & 2: The following charts show the distribution of projects/packs in two examples, a) the number of patients impacted and, b) the self-assessment score for career impact.



It is important to note that some data, like the number of patients impacted, will improve over time, whereas career impact is expected to remain stable for some time after the completion of the project

Sample Analysis:

Table 4 examines the important question CIMIT faces of funding strategies, in particular the issue of determining the effectiveness of addressing solutions through one or more individual projects. As a reminder, a project is a discrete proposal that CIMIT peer-reviewed, funded and supported. Some projects are stand-alone (i.e. one proposal was funded) and others are intertwined projects (e.g. follow-on funding for new aims or the merger of projects) that build to a solution. As the table shows, the 428 projects in the study represent 228 solutions. The table groups the data into three clusters (single, 2 to 4, and more than 5 projects per solution). As can be seen from the data, the average amount spent per project was similar per cluster, ranging from about \$95K to \$150K, while the average spent on a solution ranged by an order of magnitude, from \$95K to \$1.2M.

Table 4: Solution Cluster Analysis

Cluster: Projects per Solution	# of Solutions in Cluster	Total # of Projects in Cluster	CIMIT Funding per Project - K\$	CIMIT Funding per Solution - K\$	Follow-on Funding Ratio	Comm'l Funding Ratio	Issued US Patents / \$1M	Published Papers /\$1M
Single	162	162	95	95	8.9	4.7	4.8	24
2 to 4	49	130	149	396	10.6	18.2	16.9	41
5 to 13	17	136	148	1,183	8.6	8.5	2.7	56
Total	228	428	128	241	9.4	11	8.3	42

Note: Results are expected to change as more data and analysis is included over time

Three important observations are highlighted in yellow:

- 1) An important “academic” metric is the amount of follow-on funding that comes to the investigator to advance the CIMIT award. The data show there is no difference in getting follow-on funding based on the number of projects in a solution. This indicates that they are all likely to be similar in clinical and technical quality to be successful in convincing an academic study section or other funding advisory panel to award funding.
- 2) The “commercial” metric of commercial funding and number of patents per dollar invested were significantly higher – almost 4:1 – for the solutions that were supported with 2 to 4 discrete projects than those done as single projects and about 2:1 for those done with more than 5 projects.
- 3) Another important “academic” metric is the number of publications generated per funding dollar. The solutions (like Operating Room of the Future) in the cluster of 5 or more projects were much more productive than the others. Our hypothesis is that the scale provides a robust knowledge base from which new knowledge can be generated and disseminated.

Accelerator Update

A key conclusion CIMIT reached as a result of the initial CIS was to the need to create and implement its Accelerator Program to further improve the commercialization success rate, defined as the creation of a new start-up company outside of the CIMIT institutions or the licensing of the technology to a larger company – in short, when other groups with the primary intention of commercialization were investing their money into the project. This high success rate found in the initial study was quite surprising given that commercialization was not the primary aim of CIMIT up to that point in time (2010). CIMIT hypothesized that by applying the CIS best-practices learned, the commercialization rate (and hence patient impact) could be higher. Therefore, the CIMIT Accelerator was formed (see <http://www.cimit.org/services-accelerator.html>)

Table 5 outlines a set of the CIMIT Accelerator metrics to-date as compared to CIMIT as a whole.

Table 5: CIMIT Accelerator Performance Metrics

Metric	CIMIT Average	Accelerator Projects
Candidates Evaluated	1000 (est)	130
Solutions Funded	228	17
Selection Ratio	25%	13%
Projects Commercialized	61	7
Projects still on-going	70%	29%
Commercialization Success Rate	27%	41%
Average time to Success (months)	60 (est)	19

The results show a marked improvement in commercialization rate – from 27% to 41%. However, one cannot determine if these metrics are better because of the active role the Accelerator Team plays in the projects, or because we simply picked projects that are more likely to be commercialized. Qualitative data from the project teams does support the hypothesis that the Accelerator Team has a significant impact on the project.

Note that the ratio of projects selected is about 1/2 that of CIMIT as a whole, so the filter is more rigorous, but still much more open than typical early-stage risk capital investors (usually <1/100). Also, projects move much more rapidly through the accelerator, with time-to-commercialization reduced from about 5 years to 19 months, while also bringing the unsuccessful projects to a close much more rapidly (saving other investors more money).

Additional Lessons Learned:

CIMIT coined its approach to extracting lessons learned as “analytical anthropology”: using the data to identify trends and correlations and then using the stories of the associated projects to study and extract meaning. While that process is ongoing at this time, some important lessons learned from the prior studies are reinforced. Some examples of lessons learned include:

- **New Investigators:** Junior investigators were found to be just as successful as investigators that are more senior. Working within the CIMIT Model that includes facilitation and mentorship as well as the selection process that attempts to identify raw talent and “fresh eyes” perspectives were cited as potential equalizing factors. This supports CIMIT’s decision to proactively seek new investigators to support as the risks are lower with the support offered in the CIMIT Model
- **Prior Funding:** About 10% of the portfolio of projects received significant funding prior to receiving a CIMIT award. No difference in effectiveness was found between those with and without significant funding before receiving CIMIT’s support. This allows CIMIT select projects not likely to receive funding from other sources because they may be judged by others to be too early or risky.
- **Facilitation:** Regardless of the size of the grant or the promise of the study, targeted and skilled facilitation is a powerful combination and adds value at any stage of the innovation cycle.
- **Solutions:** Projects conducted as part of a “solution” in clusters of 2-4 projects create higher commercial output metrics as a function of input metrics than any others.

Plans Moving Forward:

CIMIT is continuing its study of the data and analysis of the contextual feedback provided by the investigators in the survey responses. A key step will be to select the core metrics that will be used in the future and a method to collapse the multi-dimensional data into a single measure that represents the “distance” along the clinical, academic and commercial axes.

CIMIT has invested considerably to build the needed infrastructure in its web-enabled platform (CoLab) to create a Clinical Impact Registry (CIR). The CIR will facilitate real time data collection and reporting on its performance and resulting clinical impact. It will allow the metrics to create a real-time “dashboard” of input, in-process and output metrics. We hope it will provide a basis for other translational research groups to benchmark and learn from each other. We also will continue to investigate new tools and have been working with the developers of the software platform Exaptive (see <https://exaptive.com>) to use data mining and visualization techniques to learn more from the rich source of data and stories available in CIMIT’s CIS.

Feedback and Benchmarks:

We are eager for your feedback and interested in any related studies or benchmarks that we can use to improve the CIS. For more information or suggestions, please contact John Collins jcollins11@partners.org

Appendix – Scales for non-numerical Metrics

Input Metrics:

<p>Investigator Seniority (HMS appointment as surrogate)</p> <ol style="list-style-type: none"> 1) Fellow or post- doc 2) Instructor 3) Assistant Professor 4) Associate Professor 5) Professor 	<p>Facilitation Score</p> <ol style="list-style-type: none"> 1) Start-up facilitation only 2) Episodic support from single resource 3) Episodic support from multiple resources 4) Ongoing, dedicated CIMIT support from single resource 5) Ongoing, dedicated CIMIT support from multiple resources
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Output Metrics:

<p>Recognition</p> <ol style="list-style-type: none"> 0) None 1) Institutional award and/or recognition 2) Regional award and/or recognition 3) National award and/or recognition 4) International award and/or recognition 5) Highest award and/or recognition in field 	<p>Career Impact</p> <ol style="list-style-type: none"> 0) No impact 1) Some impact in advancing and/or changing career path for one team member 2) Significant impact in advancing and/or changing career path for one team member 3) Some impact in advancing and/or changing career path for multiple team members 4) Significant impact in advancing and/or changing career path for multiple team members 5) Major impact in advancing and/or changing career path for one or more team members
<p>Technology Readiness Level (Adopted from the DoD)</p> <ol style="list-style-type: none"> 1) Science 2) Idea 3) Proof of Principle 4) Proof of Feasibility 5) Proof of Value 6) First in Humans 7) Validation 8) Clinical Use Approval 9) Clinical use 10) Standard of care 	<p>Patient Impact Score</p> <ol style="list-style-type: none"> 0) None 1) <10 2) 10 to 50 3) 50 to 100 4) 100 to 1000 5) 1000 - 10,000 6) Tens of Thousands 7) Hundreds of Thousands 8) Millions