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DEEP INNOVATION IN THE MEDICAL DOMAIN A LA BOSTON'S CIMIT

INSTITUTIONAL CASE STUDY



Introduction

The Consortia for Improving Medicine with Innovation & Technology (CIMIT) was established in 1998 by four leading academic medical centers and universities in the greater Boston area to leverage the value of a consortium to improve patient care through Deep Innovation using medical technology to solve pressing unmet medical needs.

CIMIT has since expanded to become the hub of a network of national and international consortia functioning as a widely disseminated 'center without walls' (Figure 1). Starting from a technological foundation of medical devices, diagnostics, and procedures, the CIMIT medical domain has grown to support a wide spectrum of medical innovations, including healthcare-related information technology, patient care workflows, drugs, and biologics. By focusing on making the network operate more efficiently, and enabling Deep Innovation rather than doing the work itself, CIMIT reduces the 'friction' of collaboration across disciplines and institutions. CIMIT's success also stems from its strict adherence to acting as, and being viewed as, 'neutral ground', with its only agenda being to help others in their journey to improve patient care.

CIMIT has built, codified, and continuously improved upon its solutions for innovation in the medical domain by facilitating and studying the journey of medical research teams working on more than 250 solutions to important unmet needs (see Further Reading). These solutions have resulted from over 600 peer-reviewed, multi-disciplinary collaborative projects. CIMIT's track record shows that building and operating an efficient virtual infrastructure to facilitate innovators within a network creates significantly more value in the medical domain than by individuals working independently.

After a brief overview of the Medical domain and associated challenges in Deep Innovation, we describe our solution – the CIMIT Model – and then conclude with illustrative case studies.

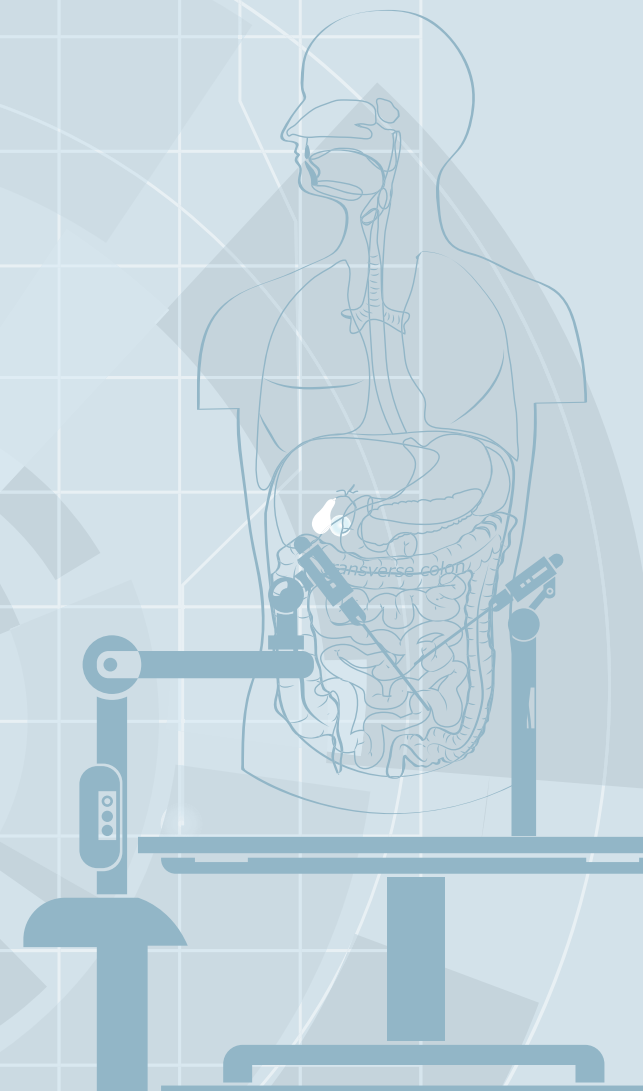
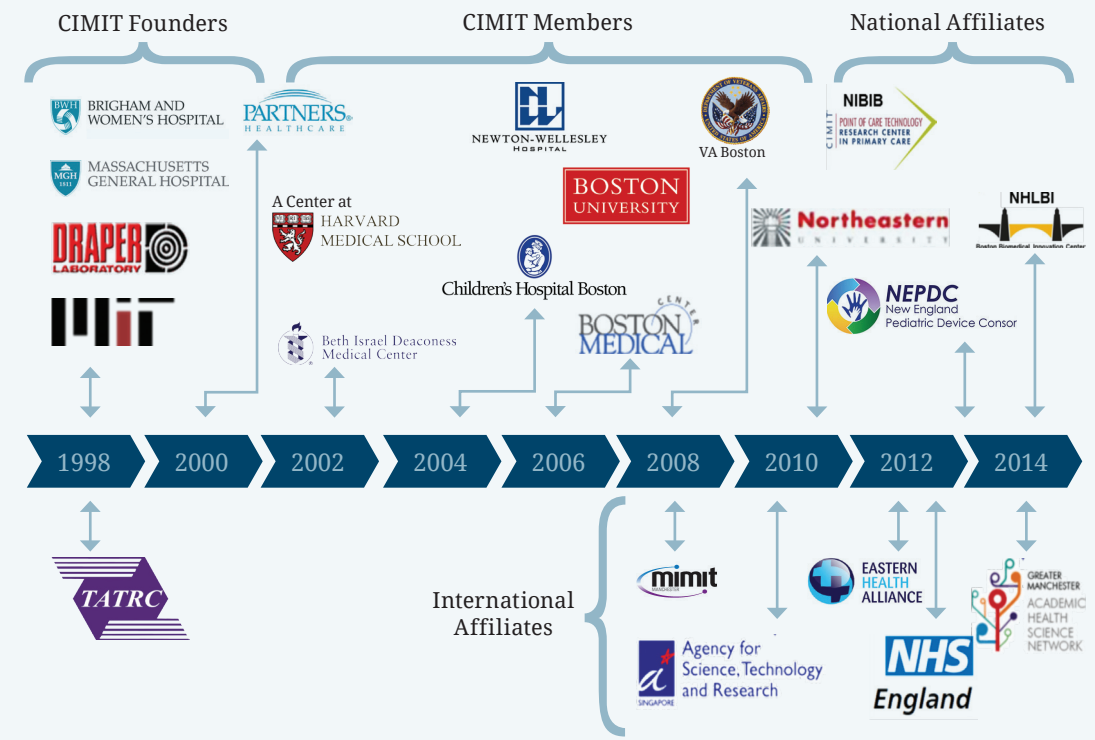


Figure 1: The growing CIMIT network
Source: Author analysis



1. The Medical domain and barriers to Deep Innovation

The process of translating medical science to patient care is complex, long, and risky. Not coincidentally, the Medical domain is in urgent need of both incremental and disruptive innovation to speed solutions to patients.

THE PROCESS OF TRANSLATING MEDICAL SCIENCE TO PATIENT CARE IS COMPLEX, LONG, AND RISKY

Medical innovation is problematic for a number of reasons. First, while academic-based medical research is a fertile source of innovative ideas and potential innovators are closest to patients (and therefore the unmet needs), academic-based medical

research has traditionally been done in silos defined by individual laboratories with minimal emphasis or value placed on multi-disciplinary, multi-institutional collaborations. Second, academic-based clinicians and engineers are not experts in the process of commercialization and are motivated and rewarded based on traditional academic metrics such as publishing and academic promotion. Finally, much of the research starts with the development of a technology, and then the investigators look for a healthcare-related problem to apply it to, which we call 'technology push', and which CIMIT has found to be less successful for improving patient care than 'clinical pull', as described in the next section. Consequently, disruptions in successfully translating academic-based innovations to patient care occur often and at multiple stages of the process, and potentially worthwhile innovations languish on the shelf.

2. The CIMIT Model: a solution to Deep Innovation in the Medical domain

To address these challenges, CIMIT has developed interrelated methods and processes referred to collectively as the CIMIT Model to 'find, fund and facilitate' collaborations that drive solutions to patient care. The CIMIT Model emphasizes the importance of starting with an intimate understanding of unmet medical needs – which we call 'clinical pull' – and then identifying collaborators to work on developing and advancing solutions to the problem, thereby improving the standard of care. CIMIT refers to the steps involved in Deep Innovation in the Medical domain as the Healthcare Innovation Cycle (Figure 2).

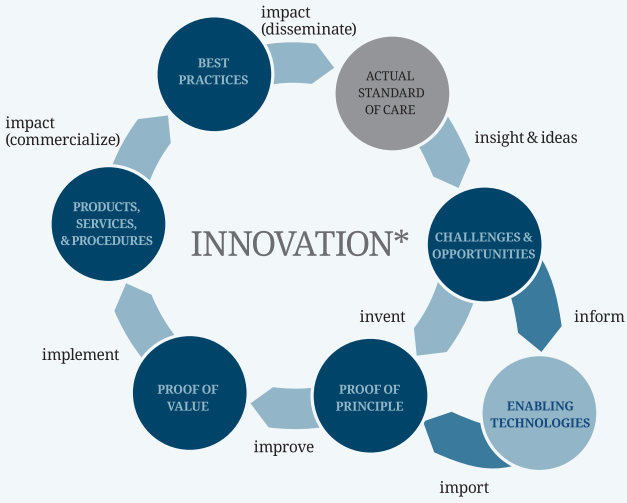
The cycle is grounded with the experience of a stakeholder, usually a clinician, observing or experiencing unmet needs and how care is actually delivered. Thus the first step is for experienced, well-informed clinicians (or other Medical domain experts) to define the problem at hand, corresponding to the Challenges & Opportunities step in the cycle. In articulating the problem, they should not be biased by any particular technological approach to a solution.

Having established an important need for healthcare improvement, innovators

then advance to the next stage of the cycle. They design potential solutions based on evaluating a range of existing technologies, or by creating new ones, and demonstrating the feasibility of the underlying principles. Robust prototypes are then developed and tested to determine whether the solution will create sufficient value under practical considerations and constraints to secure commercial investment and produce a viable offering. Evidence is gathered to achieve regulatory approval and demonstrate that the product, service, or procedure will establish a new 'best practice' in patient care. At that point, the work is still not completed; the solution needs to be broadly disseminated in appropriate venues and made widely available so that it can become the new standard of care. The cycle operates at its best as a spiral, arriving at the end of each rotation at a higher standard of care, awaiting new medical insights and innovations for further enhancement (see the case study, below, of optical coherence tomography).

Figure 2: The Healthcare Innovation Cycle

Source: Author analysis



* The process by which an unmet need is addressed by stimulating and then translating ideas and/or inventions into sustainable products or services.

CIMIT extracts insights and ideas for medical innovations through a number of convening events that bring together diverse stakeholders from industry, academia, the venture community, medical foundations, and representatives from relevant government agencies. By proactively engaging the entire community to discover, evaluate, and solve areas of unmet needs, these events stimulate novel ideas and spawn

THE EXPERTS SHOULD NOT BE BIASED BY ANY PARTICULAR TECHNOLOGICAL APPROACH

new collaborations, leveraging synergies from across different technical and clinical domains, and encouraging creative problem solving. Facilitating the formation of collaborative teams of clinicians, engineers, entrepreneurs, and companies to propose and conduct translational research is the charge of CIMIT Site Miners and Program Leaders, as well as CIMIT leadership.

Site Miners are senior members of the CIMIT consortium institutions who figuratively ‘mine’ their institution for unmet medical needs, projects, and investigators with promising ideas. They serve as the key access point to a consortium member institution. Their time and effort spent site mining is supported by their member institution. Site Miners at academic and research institutions open and maintain dialogues with the clinicians and researchers at the front lines of Healthcare and Technology within their institutions. Site Miners at companies and foundations look for strategic opportunities for their organizations to engage and help address an important business opportunity or organizational mission. Site Miners across the consortia work with each other, Program Leaders, and CIMIT leadership to find and assess areas of clinical unmet need; seek out and connect clinicians, engineers, and entrepreneurs who have creative ideas about applying technologies to solve targeted patient care challenges; provide seasoned guidance and mentorship for investigators, and serve as expert reviewers of submitted proposals. Site Miners are the glue that connects people and ideas across the cultural walls of consortium institutions and even across the boundaries separating

departments within them. Collectively, CIMIT Site Miners have thousands of interactions with innovators annually.

Program Leaders are responsible for the clinical and technical focus areas at CIMIT. They are nationally and internationally recognized authorities in one or more Medical or Engineering areas. Based out of a consortium member institution, they seek out and bring together innovative scientists, clinicians, engineers, entrepreneurs, and companies from across a consortium to solve major unmet medical needs within their particular programmatic area. Program Leaders work closely with project managers, serving as strategists, content, and industry experts, and coaches for the teams within their program area, imparting advice and offering encouragement as these researchers plan and execute projects. They help monitor the progress of teams and inform CIMIT of emerging areas of clinical need where innovation and emerging technologies could make a powerful difference in the standard of care.

CIMIT starts with a full, in-depth understanding of the unmet medical need and then conducts a deliberate, prospective, strategic planning process to select the best path forward for achieving the desired goal. Wherever CIMIT starts its involvement in the healthcare innovation cycle, its commitment and facilitation continue all the way through to patient impact.

Stages of CIMIT innovation

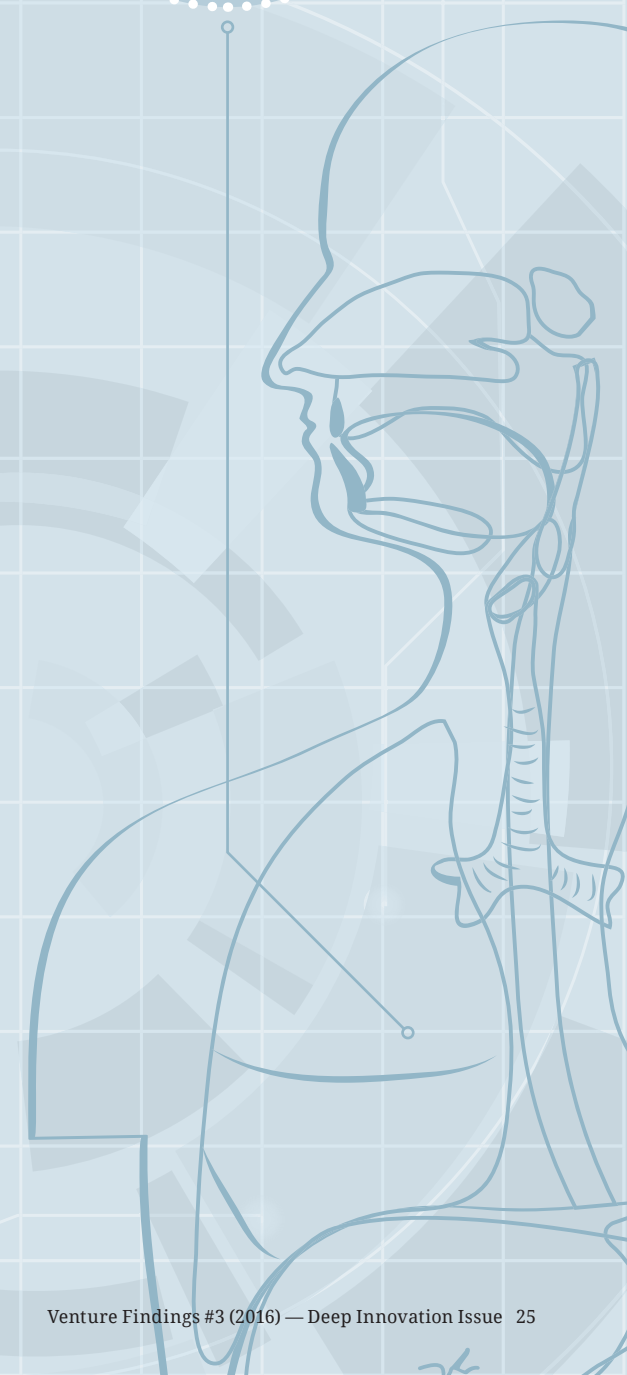
If the overall medical context of a particular unmet need is well understood, then CIMIT will begin with a small portfolio of focused projects. Mirroring the nodes of the healthcare innovation cycle, common starting points for CIMIT projects are the *innovation* stage (often called pilot, proof-of-concept, or proof-of-principle), *proof-of-value* stage (often called validation), *commercial accelerator* stage (sometimes called incubation), and *commercial growth* stage.

1. *Innovation* stage (pilot/proof-of-concept/proof-of-principle) projects are high-risk, collaborative, early-stage projects for improving patient care for existing medical fields and practices. Innovation Projects are translational in nature and typically one year in duration, with budgets (total costs) up to US\$100,000 with the objective

of scientifically de-risking a novel idea by showing early-stage proof of concept, thereby justifying proceeding on to the proof-of-value stage to generate a viable candidate for further pre-commercial development. Projects at the innovation stage are particularly difficult to fund through non-CIMIT sources given their high risk, but CIMIT has consistently secured funding for Innovation Projects based on its track record of successfully facilitating these projects to patient impact.

For an Innovation Project to be considered for funding, it must present a practical, collaborative, multi-disciplinary plan of work that will solve the addressed unmet need if successful. The criteria by which Innovation Projects are chosen for funding have been refined over the years and include: i) the work addresses an important healthcare need; ii) the work is multi-disciplinary, of high quality, and appropriately configured and resourced; iii) if successful, the project has a path forward to commercialization; iv) the solution provides a key step in moving a new capability into clinical care, and fits logically into a technology transition plan; v) the project is sufficiently novel to differentiate it from other potential solutions, but does not require any additional scientific ‘breakthrough’ to have clinical impact, and vi) risks must be recognized and addressed directly.

2. *Proof-of-value* (validation) stage projects have already been scientifically de-risked and are designed to show clinical value for the target unmet need in order to then license the technology or to receive additional funding for prototyping, technical de-risking, or early-stage, small scale translational studies. Proof-of-value projects are typically one to two years in duration with annual budgets up to approximately US\$500,000 a year.
3. *Commercial accelerator* (incubation) stage projects are scientifically and technically de-risked and have well-understood market channels, but require further development and investment of money and/or business development expertise to attract interest from an entrepreneur or commercial entity to achieve initial market penetration. These projects are typically 18 months in duration with total budgets up to US\$1–2 million. Accelerator stage projects are managed by members of the CIMIT Accelerator Team: former CEOs, or founders of medical



companies, who take responsibility for the commercialization of projects by drawing on their expertise and extended network. Through CIMIT, Accelerator Team members join projects essentially full-time to drive them to commercial success. Over the five-year history of the Accelerator Team, the CIMIT commercialization success rate has increased from 27% to 41% and the time to commercialize innovations has dropped from 36 months to 19 months, as defined by at-risk investment in moving the project towards the marketplace, typically by a commercial entity.

To maximize the likelihood of commercial success, CIMIT also offers project teams the

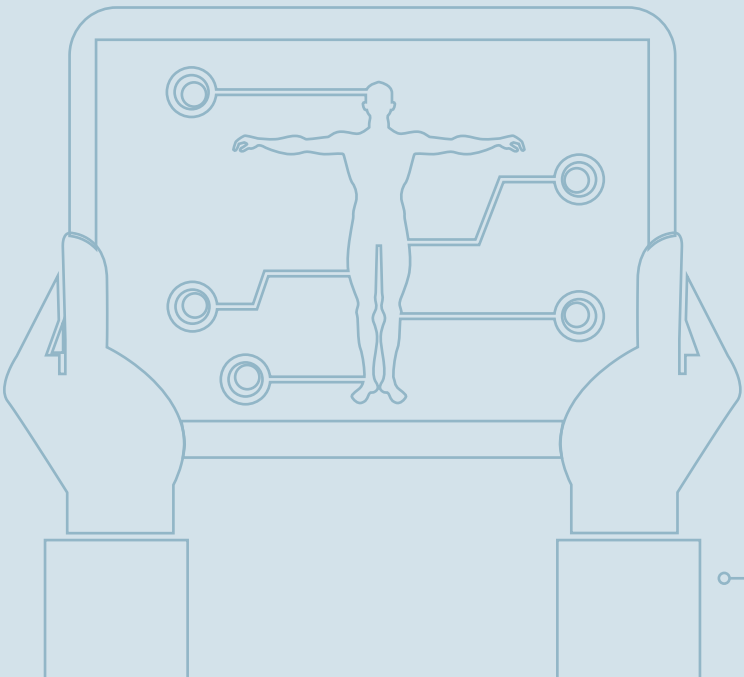
SUCH EFFORTS MAY RESULT IN A NEW FIELD OF MEDICINE

opportunity to participate in a Healthcare Commercialization Boot Camp. This is an intensive, hands-on, 10-week program that improves the commercialization effectiveness of early-stage healthcare innovations. In addition to lectures, teams receive 1:1 mentoring from successful healthcare entrepreneurs and group coaching from commercialization experts and investors. Teams develop and validate go-to-market strategies that will help secure licensing agreements and create start-ups. Real-world learning, interactive lectures, and facilitated exercises help teams define and understand the needs of key stakeholders, and de-risk the market forces affecting their projects. Led by an Entrepreneurial Leader and supported by Clinical and Technical Leaders, teams interview key stakeholders to validate value propositions, customer segments, pricing, and business models, and develop viable strategies to solidify IP and secure regulatory approval and reimbursement. The curriculum for this healthcare-specific program uniquely combines CIMIT’s proven commercialization methodologies with elements from other successful courses.

4. *Commercial growth:* besides funding projects that are pre-commercial, CIMIT funds companies to advance commercially available (or soon to be

available) products for new or expanded uses. Typically, the companies funded by CIMIT have technologies that are viewed as potential solutions to unmet medical needs but that the companies would not otherwise invest in without CIMIT support. Currently, for example, CIMIT has an ‘adoption and diffusion’ call to assist primary care practices in adopting and adapting commercially available, point-of-care technologies to demonstrate value and speed adoption in the primary care setting. CIMIT investments in companies generally require significant matching investments by the companies themselves.

In contrast to the project-level approach, if developing an entirely new medical field or inter-disciplinary effort is required to solve the unmet medical need, then CIMIT may start the process with a white paper or major convening event to define the scope of the new vision. These activities will also identify the stakeholders and the new types of collaborations and technical capabilities that will be required to move forward. Such efforts may result in a new field of medicine; re-engineered patient care environment; new national standards, or the creation of technology-, disease-, or age-specific programs. A couple of examples are highlighted in the case studies below.



CIMIT tools
Central to CIMIT’s ability to efficiently manage its processes is CIMIT CoLab®: A Collaboration Platform for Healthcare Innovation (CoLab). Steadily evolving since 2009, CoLab is a synthesis of best-in-class, secure, web-based tools with functionality designed to allow CIMIT to manage the activities of a consortium, and even more importantly, support teams through the Healthcare Innovation Cycle. CoLab is a secure, cloud-based platform with over 10,000 registered users who have engaged in more than 2,500 private collaborative healthcare innovation initiatives.

CIMIT has constantly sought to improve upon the CIMIT Model by measuring its impact. To do so, questions were asked such as: i) how often do CIMIT-funded projects proceed from being an Innovation Project to commercialization and patient impact?; ii) what are the factors that predict success?; and iii) how often do Innovation Projects get derailed, at what point(s) of the cycle, and for what reasons?

To answer these questions, CIMIT conducted a Clinical Impact Study in 2009 – updating it in 2012 and again in 2014 – to assess the outcomes of its funded projects. Each analysis was limited to projects initiated more than three years prior to when the analysis occurred in order to give projects a reasonable period of time to generate results. CIMIT leadership, with the close help of investigators and program leaders, captured,

quantified, and analyzed the impact created by the CIMIT-funded projects, including the resulting healthcare products, procedures, and services. ‘Input’ and ‘output’ metrics, such as CIMIT expenditures, publications,

WE BELIEVE THAT THIS SUCCESS RATE REPRESENTS A STEP CHANGE FOR TRANSLATIONAL MEDICAL RESEARCH

and patents were quantified, as was follow-on (or enabled) funding, defined as i) additional non-CIMIT funding to further support the project that CIMIT originally funded, and which was applied for by the project lead, or ii) commercial investment by a company.

Some key metrics of the study are presented in Table 1, which represents US\$55 million of funding for 228 solutions, many of which involved multiple, peer-reviewed projects.

While comparables are hard to identify, we believe that this success rate represents a step change for translational medical research, particularly given the early stage of development at which CIMIT often becomes involved, and, as noted above, which has further improved with the establishment of the Accelerator Team.

Table 1: CIMIT Key Outputs
Source: Author analysis

Sample output metrics		Portfolio output profile	
Follow-on funding	US\$516m	Still active	70%
Commercial investment	US\$597m	Received follow-on funding	49%
Total enabled funding	US\$1,113m	Patient trials (score >=1)	37%
Peer-reviewed publications	2,293	Significant impact on one or more careers	30%
Issued patents	458	Reached commercialization	27%
		Approved for clinical use	17%

CASE STUDIES: CIMIT

As suggested by the above metrics, the results created by CIMIT-supported projects have been substantial. Examples of large-scale initiatives and collaborative projects that have reached patient care, with hundreds more still in the pipeline, include:

1. Redesign, Reengineer Patient Care Environments Example: Operating Room of the Future (ORF)

The first and largest re-engineered patient care environment undertaken by CIMIT was the ORF, which has had a national and an international impact on the design of operating rooms, including at leading medical institutions such as Memorial Sloan-Kettering Cancer Center and New York-Presbyterian Hospital. The CIMIT Program Leader led a multi-disciplinary team to develop the ORF. Participating companies provided radio-frequency identification (RFID) capabilities for tracking personnel and equipment and a real-time integrated information dashboard for visual applications, which are now commercially available and used in major hospital systems across the U.S.

To disseminate the details about their accomplishments, the ORF team published numerous papers, abstracts, and reports, and hosted postgraduate courses and national/international site visits. The ORF became a ‘learning laboratory’ to study the effects of space re-design, process and technology innovation on patient safety, operational efficiency, and patient/provider satisfaction. This ‘learning laboratory’ was emulated by teams working on other CIMIT-funded initiatives to re-engineer patient care environments, including an ambulatory care practice and neonatal intensive care unit.

2. Develop Platform Technology Example: Optical Coherence Tomography (OCT)

OCT, a novel technology platform that provides cross-sectional images of tissue architectural microstructure at a resolution of 10 µm, was developed in 1990 at Massachusetts Institute of Technology, in part with U.S. Department of Defense funding. Two key innovators moved to Massachusetts General Hospital and received a CIMIT Innovation Project grant to develop the capability of real-time imaging of the human coronary arteries and gastrointestinal tract in vivo with OCT. Subsequent financial and business/marketing/IP support from CIMIT enabled the growth of the entire clinical OCT field. The team developed second-generation OCT that was subsequently commercialized and made imaging of coronary arteries standard practice. It also enabled the imaging of entire gastrointestinal tract organs. The successive generations of OCT and evolving uses provide a good example of the ‘spiral’ nature of the Healthcare Innovation Cycle.

Based on the work that CIMIT helped to make possible, gastrointestinal OCT and cardiovascular OCT have now been used to diagnose multiple conditions in hundreds of thousands of patients. According to a June 2015 report from BCC Research, “The global market for optical coherence tomography technologies reached US\$722.7 million and US\$795.4 million in 2013 and 2014, respectively. This market is forecasted to grow at a compound annual growth rate (CAGR) of 7.9% to reach nearly US\$1.2 billion in 2019” (<http://www.bccresearch.com/market-research/healthcare/optical-coherence-tomography-global-markets-technologies-oct-report-hlc097b.html>).

3. Setting Medical Standards Example: Medical Device Plug-and-Play

CIMIT recognized that today’s fragmented healthcare delivery paradigm has resulted in patient care technologies that are inefficient, error-prone, and subject to sub-optimal outcomes. For example, the devices used for monitoring, collecting, analyzing, and displaying critically-important device- and patient-generated data usually operate independently from each other and from the electronic medical record, each using proprietary systems. Medical devices such as infusion pumps and ventilators act autonomously to perform their functions, which may put patients at risk. Solving this problem requires the creation of new national standards in medical device interoperability. CIMIT’s Medical Device ‘Plug-and-Play’ Interoperability Program was created to address this challenge. This effort has become the national leader in developing and adopting open standards and related technologies to address key barriers to achieving device interoperability, irrespective of the manufacturer, including the development and support of suitable open standards; the elicitation, collection, and modeling of clinical use cases and system engineering requirements; the development of an open platform and tools to enable implementation; aligning clinical, manufacturer, and FDA regulatory expectations, and implementing prototype use cases in an open ‘sand box’ lab environment.

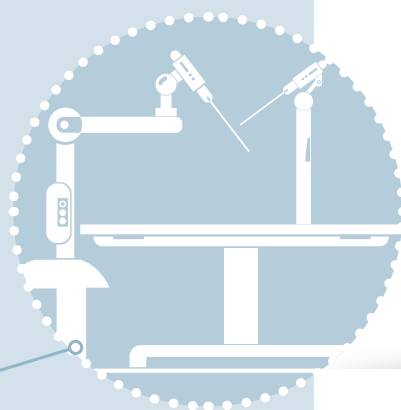
Summary

Solving today's unmet medical needs with Deep Innovation requires the removal of existing structural and cultural barriers. CIMIT has shown that its model can successfully take an idea in the medical clinic across the Valley of Death to become a transformative new standard of care.

CIMIT is now optimizing its processes for linking hubs of medical innovation across the world into a network of consortia to address important regional healthcare imperatives, often with the local support of government agencies that have identified opportunities for economic growth through the development of their medtech/biotech sectors. CIMIT will then scale, replicate, improve, and adapt its processes in these hubs to facilitate Deep Innovation in medicine and, as a global collaboration, to collectively pursue our mission to improve healthcare.

Acknowledgements

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FURTHER READING

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