Accelerating Commercialization of Cost-Saving Health Technologies

MAY 2012
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The von Liebig Center for Entrepreneurism and Technology Advancement at UC San Diego Jacobs School of Engineering is dedicated to accelerating the translation of University technologies to benefit society. Through a combination of grants for proof of concept, business mentoring, and entrepreneurial education, the von Liebig Center guides faculty and university inventors through the technology commercialization process.

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In January 2012, *The Scientist*, a magazine covering research and technology in the life sciences, selected a pocket-size holographic microscope with cell phone connectivity as the top innovation of 2011. The device, known as LUCAS (Lensless Ultrawide field Cell monitoring Array platform based on Shadow imaging), was developed by a professor of electrical engineering and bioengineering at the University of California at Los Angeles (UCLA) as a way to support disease diagnosis in resource-poor and remote regions.

Dr. Aydogan Ozcan’s invention could cost less than $10 in materials and has the potential to replace advanced microscopy instruments in the field. The device exemplifies a new wave of health technology that entrepreneurs and researchers are developing worldwide. These new technologies harness advances in information and communication technologies to improve healthcare access, as well as efficiency and affordability. Ultimately, the technologies could play a role not only in improving care throughout the developing world, but also in helping address the enormous health challenges of aging, obesity, and chronic disease in the United States.

Yet despite the enormous potential of inventions such as LUCAS—and the growing importance of universities as sources of innovative technologies—academic researchers face significant hurdles in commercializing university-originated inventions. These barriers range from difficulty attracting risk capital to a lack of the expertise needed to fully develop and market a new invention. The result is that many promising new technologies never make the transition from laboratory to market.

Fortunately, a number of public- and private-sector leaders are working to bridge the gap between university research and industry through a variety of approaches, including impact investing, open innovation partnerships, innovation challenges, and university gap funding programs. Because these strategies are still relatively new, stakeholders continue to experiment with a variety of techniques, such as targeting a specific stage of the commercialization process and pursuing unconventional collaborations between competitors.

In 2011, the William J. von Liebig Center for Entrepreneurism and Technology Advancement at UC San Diego, in partnership with the California HealthCare Foundation, Robert Wood Johnson Foundation, and Booz Allen Hamilton, launched a regional initiative called the Southern California Health Technology Acceleration Program (HTAP). The program was created to provide researchers from universities and research institutes in southern California with funding and business mentoring to commercialize technologies that reduce healthcare costs and expand access for the underserved. HTAP represents a unique approach for addressing the commercialization challenge, in that it combines a regional model for a technology accelerator with the specific focus of supporting cost-saving health technologies at the proof of concept (POC) stage of development.

In fall 2011, HTAP chose four teams of scientists, including Dr. Ozcan’s research group, to receive up to $100,000 each to advance their technologies toward commercialization. As part of that process, the awardees are now engaged in a year-long partnership with the von Liebig Center that includes business
mentoring and funding to demonstrate POC. Because additional development will likely be required before the products can actually come to market, the full impact of the HTAP initiative will not be measurable for some time. What is already clear, however, is that inventions such as LUCAS now stand a better chance of surviving the commercialization process, thanks to HTAP. These improved odds mean that patients around the globe are more likely to realize the benefits of technologies that can increase access to high-quality care at a lower cost.

Photo 1. LUCAS Holographic Microscope

This report highlights opportunities for accelerating the commercialization of cost-saving health technologies and explores how HTAP’s sponsors are attempting to give innovative technologies a better chance of making a successful transition to the marketplace.

Section 2 discusses the imperative for health innovation and describes an emerging breed of lower-cost health technologies. Section 3 highlights several of the challenges associated with early-stage technology commercialization and outlines some approaches for bridging the gap between university research and industry. Section 4 shares the story of HTAP and the four selected projects.

The final section of the report discusses what lies ahead for the HTAP awardees while offering considerations for government, academic, and commercial stakeholders based on insights gained from the HTAP experience so far.

Common Commercialization Terms Found In This Report

Technology Accelerator—a program that provides funding, services, and support to researchers and entrepreneurs with the goal of accelerating the development and commercialization of early-stage technologies.

Proof-of-Concept (POC)—a process designed to determine the market feasibility of an invention by defining technical performance against market needs.

Angel Capital—risk capital supplied by individual investors, generally in return for equity in start-ups and early stage companies. Angel investments are often in the range of $100,000–$500,000.

Venture Capital—risk capital supplied by a venture capital fund, a type of firm whose managers and investors deploy capital in exchange for equity in high-growth private companies. Venture capital investments are often in excess of $2 million.

Stages of Development

• Seed/Start-Up—company has a concept or product under development, but is likely not fully operational.

• Early Stage—company has a product or service in testing or pilot production. The product may be commercially available and generating revenues.

Impact Investing—making investments with the intent of creating positive social impact beyond a financial return.

Asymmetric Risk Profile—an imbalance between the potential risk and reward for a given investment.

Incubator—a program or organization that provides entrepreneurs with services and resources designed to accelerate successful development of new companies.

Crowdfunding—an approach for obtaining risk capital by attracting a “crowd” of investors, each of whom makes a small investment to collectively address capital requirements.
As the US Supreme Court considers the constitutionality of the Affordable Care Act, and America gears up for another presidential election, nearly all political and business leaders agree on one thing: The current trend of growth in health spending is unsustainable, and failure to slow that growth puts the nation at risk of serious economic harm.

For more than a decade, health spending has consistently outpaced gross domestic product (GDP) and wage growth. The Centers for Medicare & Medicaid Services (CMS) projects that national health expenditures will reach nearly 20 percent of GDP by the end of this decade. During this period, the government’s share of spending could reach 50 percent, and personal out-of-pocket costs may increase by as much as 40 percent.

Leading policy voices, such as the Commonwealth Fund and Brookings Institution, suggest that slowing spending and transforming the health system will require significant innovations in access, payment, care delivery, and patient empowerment. Most also believe that better information tools and technology are key for transformation. Costly medical technologies and related changes in medicine have been estimated to drive 50 percent or more of spending growth. However, health information technologies (health IT), such as electronic health records, are considered foundational for enabling the necessary reforms. Further, some thought leaders have recognized that new health and medical technologies can also play a key role in enabling transformation.

New Breed of Health Technology

Between the two extremes of high-cost medical technologies and efficiency-driving health IT, a new generation of cost-saving health technologies is emerging. These new innovations are appearing at convergence points across the healthcare, life sciences, information technology, and telecommunications industries. (See Figure 1 on following page.) As with LUCAS, they are often platform-based inventions applicable to multiple conditions and with potential value in the United States, as well as the developing world.

The researchers and entrepreneurs developing cost-saving health technologies are anticipating new payment scenarios that favor early diagnosis and prevention, rather than capitalizing on wasteful, volume- and intensity-based reimbursement models. Instead of high-cost, narrow-use medical technologies and health information systems designed for billing, these inventors are leveraging technological advancements, such as microelectronics, low-power sensors, wireless networks, and cloud computing, to transform delivery processes and challenge traditional cost structures.

If innovators are successful in bringing these inventions to market, cost-saving health technologies can be applied to help improve prevention, diagnosis, and treatment of disease. At the same time, they will enable the redistribution of care away from costly acute environments, thereby promoting more efficient use of clinical resources.
The Role of University Research

Despite significant opportunities for the development of disruptive products and services in the health industry, large healthcare, life sciences, and technology companies struggle to keep pace with demand for continuous innovation. The challenge of developing new technologies in many large firms stems from several issues. From the perspective of senior leadership and investors, introducing new offerings makes performance difficult to predict. As a result, executives and shareholders often shy away from risks that could undermine or cannibalize existing revenue streams. In addition, a majority of employees in large companies lack an entrepreneurial mindset because they serve in operational roles that reward performance rather than risk.9

Corporate research and development practices have also undergone significant changes in the last 40 years. The traditional research and development (R&D) model—in which companies invested in internal research and benefited from a virtuous cycle of profitable innovation and reinvestment—has steadily eroded, causing large companies to increasingly rely on external collaborations for developing and diffusing innovations.

As the environment has shifted, universities have emerged as an increasingly important source of external ideas and foundational technological advancements.10 Universities have a rich history of research in healthcare and technology and have produced breakthrough innovations that spawned multibillion-dollar industries in areas such as biotechnology and the Internet.

Yet even with many compelling examples of value creation, the gap between university research and industry remains wide. When compared with the long tradition of internal corporate R&D, engaging faculty and researchers in the commercialization of their ideas is a fairly recent development. As a result, a dearth of capital, knowledge, and support for applied research frequently prevents or delays innovations from reaching the market.

Genentech: University Research Spawns $100 Billion Industry11,12

During the last quarter of the 20th century, university-originated technology for genetic engineering brought biotechnology to the forefront of research and innovation. In 1976, University of California San Francisco (UCSF) Professor Herbert Boyer and venture-capitalist Robert Swanson founded Genentech, the world’s first biotechnology company. Boyer and Swanson each committed $500 to create a business that would aim to find commercial applications for recombinant DNA technology that Boyer had developed with Stanford geneticist Dr. Stanley Cohen 3 years earlier.

By 1977, Genentech reported the production of the first human protein manufactured in bacteria, an event often considered the birth of the Age of Biotechnology. One year later, in the laboratories at UCSF, Boyer cloned the human insulin gene using recombinant DNA technology, creating the foundation for an unlimited supply of insulin.

The global biotechnology industry has since become a $100 billion per year business. In 2009, Genentech became a wholly owned subsidiary of Swiss pharmaceutical and diagnostics company, Roche, following a $47 billion acquisition of the 44 percent of Genentech shares not already owned by Roche at the time.
THE CHALLENGE OF COMMERCIALIZING EARLY-STAGE HEALTH TECHNOLOGIES

Difficulties of Commercialization
When attempting to commercialize a technology, researchers face challenges surrounding the nature of their invention, the support mechanisms that may or may not exist at their particular institution, and the inherent risk of failure during the early stages of development. While each researcher’s journey is unique, four possible impediments—access to capital, potential limitations of traditional technology transfer, the need for entrepreneurial skills, and the difficulty of navigating the complexities of the healthcare market—are common roadblocks.

Lack of Risk Capital. Changing investment dynamics over the last decade have created a critical gap in access to capital between grants for basic research and venture capital. At one end of the spectrum, government funding remains largely focused on basic, unapplied research. On the other end, less angel and venture capital is available because investors have increasingly channeled their capital toward later-stage companies already poised for commercial growth.

Data from PricewaterhouseCoopers and the National Venture Capital Association show that total venture capital allocated to companies from seed/start-up to later stage fell dramatically between 1999 and 2011, from $22.4 billion to $6.6 billion, with total seed/start-up investment decreasing by a factor of almost 10.\(^{13}\) While the amount invested in 1999 clearly reflects a period of inflated investment volume and expectations associated with the height of the “dot com” bubble, the shift in relative share of venture capital by stage in the years since has nonetheless been revealing. Between 1999 and 2011, the value of seed/start-up investments decreased from 5.5 percent to just 2 percent of total funding, while investments in early-stage companies grew from 23 percent to nearly 35 percent of the total. (See Figure 2 on following page.) These changes in relative share of capital across earlier stages of investment demonstrate a clear migration toward less risk and proven companies, irrespective of the aggregate amount invested in a given year.\(^{14}\)

Research by the Center for Venture Research (CVR) at the University of New Hampshire has shown that angel investing also has decreased and shifted toward lower risk areas over the last decade. CVR data reveals that total angel investment has decreased by a third, from more than $30 billion in 2001 to approximately $20 billion in 2010. Although angel investors favored early-stage investment in 2002 (47 percent of total investment), seed/start-up stage investments declined to just 31 percent of angel capital in 2010.\(^{15,16}\)

While there may be cases where angel and seed-stage investors fund applied research and POC projects, trends in venture and angel capital suggest that fewer and fewer are willing to gamble at these stages. Further, in the case of health technology innovations predicated on achieving dramatic cost reduction, it may simply be unrealistic to expect the level of return typically required for high-risk, early-stage investments.

Health technology innovations predicated on achieving dramatic cost reductions may not be able to provide the level of return that is typically expected in exchange for high-risk, early-stage investments.
Potential Limitations of Traditional Technology Transfer.
In 1980, the passage of the Bayh-Dole Act enabled universities to retain ownership of intellectual property developed under federally funded research and sparked the rise of university technology transfer offices (TTO). According to the Association of University Technology Managers, Bayh-Dole has fueled significant growth in commercialization of university inventions, including formation of more than 5,000 new companies.17

Over time, however, TTOs have struggled to match the pace of university-based innovation, and the limitations of the traditional technology transfer system have become a potential barrier to commercialization. In response to chronic underfunding and sometimes constraining rules of traditional technology transfer, many universities are working to make the technology transfer process faster and more business friendly. A growing number of institutions are also incorporating options that enhance TTOs with programs to directly fund and incubate companies founded on university research.

Mindset of Academic Researchers. In cases where funding and technology transfer limitations can be overcome, early-stage commercialization still requires additional knowledge and skills that university researchers frequently do not possess. Academics have historically operated in an environment where profit is not a key motivation. Instead, publication, peer recognition, and the education of students have been the principal rewards for their efforts. However, increasingly structured university technology transfer processes, as well as a desire to move research beyond the laboratory for both public and personal benefit, have led many researchers to pursue patents and intellectual property rights in the interest of commercialization.

Even so, researchers often face misalignment between their academic interests and incentives (e.g., publications, tenure), and the expertise necessary to efficiently move their concepts toward commercialization. Converting research to a product or process typically requires a market-ready technology, a viable business model, proof of market need, and business-oriented management skills. According to Rosibel Ochoa, PhD, executive director of the von Liebig Center, “Most academic researchers have no interest in becoming entrepreneurs, and few can successfully commercialize their inventions without guidance, collaboration, and an ecosystem of support.”

Complexity of the Healthcare Market. Healthcare is a complex and highly regulated industry that is subject to a patchwork of federal, state, and local laws and regulations. A highly fragmented delivery system and indirect payment mechanisms can further cloud a researcher’s path to sales and scale, making it difficult to attract investment capital. Beyond funding, researchers must also anticipate consolidated influence in markets with high levels of payer and provider concentration, as well as risk-adverse regulatory agencies and intense competition from direct competitors or potential substitutes.

Adding to the complexity of the market is the transitional state of business models in the healthcare industry. While fee-for-service reimbursement remains the dominant form of payment, a wave of disintermediation and risk-shifting is migrating payment increasingly toward outcome-based models and accountability for total cost. These changes present opportunities for health technology innovators, but are also a moving target. “The days of
“Without financial support for low-cost health care innovation, the research we do at the Institute and the work other agencies, institutions, and entrepreneurs are undertaking will have a tougher path toward becoming a reality and actually lowering health care costs for the public.”
— Gary West, chairman and founder of West Wireless Health Institute

building your business model around a CPT code area numbered,” said Timathie Leslie, a vice president at Booz Allen Hamilton. “Researchers and entrepreneurs developing new health technologies will increasingly need to demonstrate outcomes and value in an environment of risk-based payment.”

Approaches to Bridging the Gap

Stakeholders are attempting to bridge the gap between university research and industry through a variety of approaches, including impact investing, open innovation partnerships, innovation challenges, and university gap funding programs. Each of these offers potential value to university researchers, and all may serve as tools for accelerating commercialization of cost-saving health technologies.

Impact Investing. Impact investments generally are debt- or equity-based investments made by foundations that are designed to “achieve a type or scale of social impact that they could not achieve through grantmaking alone.” Impact investing enables foundations to deploy additional capital based on highly specific programmatic and investment goals, without disrupting the core mission and strategy of the organization. Foundations may invest directly in companies or gain exposure indirectly through alternative vehicles, such as commitments to funds or fund portfolios that invest in mission-aligned sectors and opportunities.

Impact investors’ ability to accept alternative or less demanding return metrics creates a unique opportunity to support commercialization of early-stage health technologies. Given sufficient mission or program alignment, foundations can overlook asymmetric risk profiles and accept technology value propositions that hinge on indirect savings—such as avoiding a more costly procedure downstream—and reductions to the total cost of healthcare. “Traditional investors usually focus on high-cost and high-tech advancements to support large investments with potential for significant profits,” said Margaret Laws, MPP, director of the California HealthCare Foundation’s Innovations for the Underserved program. “Foundations can play an important role in enabling lower-cost, high-quality care by funding cost-saving health technologies.”

Open Innovation Partnerships. The term “open innovation” gained attention nearly a decade ago when Henry Chesbrough wrote about a new model of innovation in which companies commercialize both internal and external innovations while considering alternative pathways for their own ideas beyond their current businesses. In the evolving paradigm of open innovation, the traditional R&D monolith is transformed into a more loosely coupled architecture focused on the funding, generation, and commercialization of innovation. This more flexible model enables companies to make strategic decisions about how they engage with external partners and what roles to play in the process of innovation. (See Figure 3.)

Figure 3. Open Innovation Model

The open innovation paradigm represents a strong value proposition for the health industry and provides clear benefits for early-stage technology commercialization. In recent years, organizations such as Pfizer, GlaxoSmithKline, and Eli Lilly have turned to open innovation partnerships as a way to leverage their capital, infrastructure, experience, and distribution capabilities to accelerate commercialization of new therapies.\(^2^1\) As the transition toward outcome-driven payment models and personalized medicine accelerates, greater collaboration will be required among pharmaceutical, medical device, and technology firms in areas such as companion diagnostics—diagnostic tests used to select or modify use of a therapeutic agent—and the integration of genomic and electronic health record data.

**Innovation Prizes and Challenges.** In 2009, McKinsey reported that the use of awards and prizes has increased dramatically over the past three decades.\(^2^2\) Awards have evolved from a tool primarily used for recognizing achievement to a system designed to produce innovations in areas such as space, the environment, and science and engineering. Over the past 5 years, the total value of challenge-based innovation funding has increased significantly, with large prizes pushing the total estimated value of the market for prizes and challenges to between $1 billion and $2 billion.\(^2^3\)

Within this growing market, healthcare has attracted an increasingly large and diverse pool of challenge-based innovation prizes. Corporate- and foundation-sponsored challenges in healthcare currently range from small prizes for innovative health IT applications to GE’s $100 million challenge focused on accelerating the detection and personalized treatment of breast cancer.\(^2^4\)

The federal government also has committed significant funding toward prizes and challenges through initiatives such as the Medical Innovation Prize Act of 2007, which established a pool of $80 billion for development of novel therapies. More recent efforts include energy and health innovation challenges, as well as establishment of an online clearinghouse for government prizes.\(^2^5\),\(^2^6\)

The challenge-based approach offers complementary value for multiple stakeholders, including researchers, companies, foundations, and government. “Point solution” challenges—those that seek innovation to solve a specific, well-defined problem—create pathways for researchers to efficiently bring their products to market, while at the same time significantly reducing the risk of investment for companies or funding organizations. Other types of challenges, with goals such as market stimulation or community building, can indirectly support early-stage development and accelerate commercialization by helping define market frameworks or product pathways and by creating ecosystems of support and capital around researchers.

**University Gap Funding Programs.** A gap fund is generally defined as monies “managed either internally or externally to the research institution to bridge the funding gap between federal funding of research and ‘first money’ from outside investors.”\(^2^7\)

Universities or partnering organizations have developed gap funding programs to augment their traditional technology transfer processes and thus increase and accelerate commercialization. Programs vary widely in size, structure, approach, and commercialization priorities, but can be generally segmented into four primary fund types: (1) translational research, (2) POC, (3) business formation, and (4) business growth. Funding typically is distributed in the form of grants or investments that range from as little as $20,000 up to $1 million.\(^2^8\)

A 2011 survey of gap funds revealed a number of benefits, including high rates of commercialization, improved success in securing early-stage capital, and better organizational returns.\(^2^9\) (See Figure 4 on following page.) In many cases, a critical aspect of the gap fund value proposition is the cultivation of an ecosystem that supports researchers and entrepreneurs by helping them address specific goals and requirements at each stage in the commercialization process.
Figure 4. Gap Funding Within the Landscape of Early-Stage Funding

Source: Adapted from Jacob Johnson, “Mind the Gap: The University Gap Funding Report,” Innovosource, LLC, 2012

SBIR = Small Business Innovation Research; STTR = Small Business Technology Transfer
HTAP is an example of a gap funding program that leverages impact investments from funders of the initiative. It was created by the William J. von Liebig Center for Entrepreneurism and Technology Advancement at the UC San Diego, in partnership with the California HealthCare Foundation, Robert Wood Johnson Foundation, and Booz Allen Hamilton. HTAP is a competitive program to accelerate commercialization of university research on health technologies with potential for reducing healthcare costs and expanding access for the underserved. It focuses on the POC stage of development, while using a regional technology accelerator model to identify novel, cost-saving health technologies.

The William J. von Liebig Center
The von Liebig Center offers programs and services to faculty, researchers, and students interested in commercialization of the inventions resulting from their research. At the core of its strategy is the commercialization milestone known as the POC.

The POC process is designed to determine the market feasibility of an invention by defining technical performance against market needs, thus delivering high-quality candidates with better odds of commercial success. At the POC stage, a combination of seed funding for prototype development and a sound commercialization plan significantly increase the value of the technology, making it more attractive to investors and entrepreneurs.

In 2010, the U.S. Army Telemedicine and Advanced Technology Research Center (TATRC) and Qualcomm Inc. provided the von Liebig Center with grant funding to adapt its POC process as part of a regional wireless health technology acceleration program. The initiative sought to identify and accelerate the commercialization of university and research institute technologies in wireless health that could address medical needs of military personnel and their families.

William J. von Liebig Center for Entrepreneurism and Technology Advancement at University of California San Diego
The von Liebig Center was founded in 2001 “to accelerate the commercialization of UC San Diego innovations into the marketplace, foster and facilitate the exchange of ideas between the University and industry, and prepare students for the entrepreneurial workplace.” Since inception, the center has been involved with more than 300 projects, advised more than 200 faculty members and graduate students, awarded $4.6 million in pre-seed grants to 82 projects, and supported the creation and growth of 32 start-up companies. Collectively, these companies have created more than 200 jobs and have received more than $100 million in follow-up private capital to date.
A Unique Program
Using the wireless health technology acceleration initiative as a model, von Liebig and HTAP sponsors set out to create a unique program that would maintain a regional focus, yet broaden the landscape of potential applicants by removing the explicit requirement that health technologies be wireless. In addition, HTAP aimed to differentiate itself from other technology accelerators by qualifying applications based on their ability to reduce cost, rather than relying strictly on the invention’s profit potential.

In the HTAP process, applicants were first required to submit a statement of intent (SOI), including an overview of the technology and proposed application. SOIs guided recruitment of a suitable panel of independent expert judges and facilitated the initial screening of applicants based on eligibility, stage of development, and program fit. Following a secondary screening and selective invitations to submit a full proposal, a final round of 12 participants was invited to compete for one of four awards of up to $100,000, along with a year of business mentoring from a von Liebig advisor.

Application Results. At the outset of the program, von Liebig coordinated outreach with other universities and research institutes in the Southern California region to recruit potential applicants. HTAP received 64 SOI responses from 11 institutions across the region. SOIs from UC San Diego, University of California at Irvine (UC Irvine), UCLA, and the University of Southern California (USC) represented almost 90 percent of the respondents. The remaining 10 percent originated from hospitals, research institutes, and a foundation. A majority of submissions were led by one or more faculty members from institutions’ schools of engineering or medicine, with approximately one in four applications coming from multidisciplinary teams representing both disciplines.

Applicants proposed projects across five categories of health technology spanning a range of technology risk. These included Care Delivery Efficiency and Outcomes, Behavioral Interventions, Diagnostic and Monitoring Devices, Surgical and Therapeutic Devices, and Therapeutic Agents. The largest share of applicants (36 percent) proposed projects for Diagnostic and Monitoring Devices, while Therapeutic Agents were proposed in only 4 percent of SOIs. Approximately one-third of all applicants believed their

Figure 5. Number of SOIs by Technology Category

Source: von Liebig Center Analysis
technology would directly lower the cost of delivering healthcare, while the other two-thirds suggested their products would improve patient access, improve the quality of care for a particular setting, or both.\textsuperscript{30}

More than 20 SOIs proposed diagnostic and monitoring technologies, which may contribute to early disease detection when treatment is more effective and less expensive. Devices for remote monitoring can also reduce cost by facilitating continuous data collection and reporting to provide potential warnings of more serious episodes of illness. Benefits can include a decrease in frequency of hospitalization and reduced chance of readmissions.

Only six SOIs proposed technologies for behavioral intervention. The number of submissions was notably low given the growing level of attention to prevention and wellness among health plans, employers, and providers with the need to contain healthcare costs. Obesity and other lifestyle-related risk factors significantly increase the odds of developing costly chronic conditions such as diabetes, hypertension, and heart disease. Therefore, changing consumer behavior is essential to preventing the onset of these conditions or improving the ongoing management of chronic disease once it does occur.

It is unclear why so few applications targeted behavioral interventions. One reason may be that the intense focus on wellness within the health industry and the emerging science of behavior change are both relatively recent developments. Researchers may also assume that entrepreneurs who are focused on behavior change will leverage existing technologies, rather than look for opportunities to commercialize new discoveries. Whatever the reason, projects such as the “Mobile Mandometer” (see photo)—a mobile solution for at-home weight normalization proposed by Dr. Michael Leon at University of California at Irvine—demonstrate the potential power of cost-saving health technologies that focus on changing behavior.

**Screening Process.** All SOIs were initially screened according to basic eligibility requirements, responsiveness to program goals, and whether the project was beyond the POC stage. (See Figure 6 on following page.) The 28 SOIs that passed this initial screening were evaluated by an expanded panel of reviewers based on a comparison of relative medical importance and technological novelty.

The 12 finalists were each paired with a von Liebig advisor to prepare for in-person presentations to a panel of independent expert judges at the von Liebig facilities in San Diego. Judges used a weighted scoring system and force ranking to select four tentative winners, including Dr. Ozcan, to receive up to $100,000 to advance their technologies toward commercialization. The awardees were then subjected to a period of due diligence to address any open questions from judges and to verify patent filing status. The winners then worked with their von Liebig advisor to create a technology development plan, budget, and grant payment milestones. This initiated the year-long mentoring program.
**Figure 6. HTAP Screening and Selection Process**

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<td>Researchers begin by submitting a statement of interest (SOI), including an overview of their technology and proposed application</td>
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SOIs screened for:
- Eligibility
- Fit with impact/interest areas
- Stage of development

Expanded panel reviews SOIs for:
- Relative medical importance
- Technological novelty

Finalists present to a panel of expert judges

Due diligence on tentative winners:
- Open questions
- Patent filing status

Awardees work with a von Liebig Center advisor to develop their plan, budget, and payment milestones

Source: Booz Allen Hamilton and von Liebig Center
HTAP WINNERS

Awards were made to four teams of scientists from UC Irvine, UC San Diego, and UCLA, representing two early-stage companies and two teams with pre-incorporation stage research. The winning projects consisted of two point-of-care diagnostic tools, a cloud-based patient treatment planning system, and a smartphone-based weight-loss management tool. Both diagnostic tools were platform-based innovations with application for multiple diseases, while the treatment planning and behavioral intervention technologies targeted cancer and obesity, respectively. All winners incorporated at least two of the key enablers for cost-saving health technologies—microelectronics, low-power sensors, wireless networks, and cloud computing.

Microscopy on a Cell-phone as a Diagnostic Tool (LUCAS)
Aydogan Ozcan, PhD, University of California, Los Angeles

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<td>Diagnostic and Monitoring Devices</td>
<td>Cost, Quality, Access</td>
<td>Microelectronics, Sensors, Wireless</td>
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This UCLA group pioneered a lens-free, on-chip imaging modality termed LUCAS, which enables conventional cell-phones to be converted into microscopes and diagnostic tools, providing an important solution to various rural medicine needs. The first application for LUCAS is the Complete Blood Count (CBC).

Morbidity and mortality are disproportionally high in children from resource-poor settings and disenfranchised populations, particularly those living in rural or inner city areas of the United States. Poverty, poor access to healthcare, poor nutrition, and low level of parental education are predisposing factors. One major problem affecting young children in disenfranchised populations is vulnerability to infection followed by anemia and poor nutrition. A critical laboratory test for aid in diagnosis and management of these conditions is a CBC, one of the most widely ordered laboratory tests in medicine.

With instant availability of CBC results, physicians, physician assistants, or nurse practitioners will be in a better position to make a diagnosis and prescribe the right drugs during an initial patient contact that can take place practically anywhere, with less reliance on a return visit (a notorious compliance issue in poor communities). The platform can also be used, through telemedicine, to guide referral to other medical services. Further, by doing tests in-house rather than sending the blood specimens to outside laboratories, the provider can capture significant additional value for themselves or their institution. This is of particular importance for many organizations that are chronically underfunded and dependent on government or philanthropic agencies.
Low-Cost Semiconductor Test Strips for Accurate In Vitro Diagnostics

Chi On Chui, PhD, University of California, Los Angeles

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This project seeks to exploit a low-cost, nano-engineered sensor technology for rapid, point-of-care diagnosis (e.g., in the Emergency Department, Intensive Care Unit, ambulance, physician’s office, etc.). POC data has been obtained and demonstrates 10 times greater sensitivity, with results available in minutes. The first diagnostic targets for this technology are the cardiac injury markers that appear early in blood samples, but are in very low concentrations immediately following heart attacks. This platform technology will be packaged in a simple handheld reader interfaced with a disposable test strip and will ultimately be applied to other disease diagnostics in point-of-care scenarios where ease of use, fast results, and low cost are critical for adoption, especially in areas where healthcare resources are inadequate.

GPU and Cloud-Based Next-Generation Cancer Radiotherapy Treatment Planning

Steve Jiang, PhD, and Yuanyuan Zhou, PhD, University of California, San Diego

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In the United States, about two-thirds of cancer patients are treated with radiotherapy to deliver a lethal dose of radiation to the tumor to kill cancerous cells while sparing surrounding healthy organs and normal tissues. The treatment is complex and highly patient specific. Treatment planning is conducted by planners using a dedicated computer and software system called a “Treatment Planning System.” A finished treatment plan needs to be carefully inspected and approved by the attending physician before it can be used to treat the patient. The current treatment planning systems are expensive, and the process of planning is inefficient. It often takes 1 to 2 weeks before a clinically acceptable treatment plan is achieved and approved by the physician. Moreover, treatment data is stored in individual institutions and in various formats, so it is costly to maintain the data and difficult to share the data among institutions.

In this project, the investigators will develop a next-generation, web-based treatment planning system employing graphics processing unit (GPU) software and “cloud” computing. Treatment planning will be performed “in the cloud,” and hospitals will simply pay a fee for processing each plan. Moreover, with this system, the GPU-based computation engine is used to speed up the computationally intensive tasks in the planning process, such that an optimal treatment plan can be accomplished very rapidly and using significantly less physician time. Combining the benefits of cloud computing and GPU high-speed processing, the new system will reduce the cost of treatment planning, better use professionals’ time, encourage treatment data sharing, and improve the utilization of radiotherapy devices.
The Mando Group has developed what appears to be an effective treatment for obesity, but thus far has only demonstrated the therapy in a relatively expensive clinic-based program where obese patients are trained to normalize their food intake pattern using feedback about their eating behavior during and between their meals. Patients eat their meals with a Mandometer® (mando means “I eat” in Latin), which consists of a scale that sits under a dinner plate that sends information about their eating behavior to a small monitor. The eating behavior of a normal-weight person consuming the same meal is also shown on the monitor, allowing patients to model their eating behavior to the normal pattern. Such training allows them to learn the normal feelings that guide healthy weight individuals to terminate meals.

To make this program available to many more people, this group proposes to reduce the cost of treatment by moving it out of the clinic. They will use the power of the iPhone and Android operating systems to develop: 1) a mobile mealtime feedback device that will help patients learn to recognize satiety during a meal, 2) a mobile device to train people to eat only when they are hungry, and 3) a mobile virtual therapist, which uses an avatar to answer the more than 4,500 questions that have arisen in their previous interactions with patients, providing the additional practical support needed for an effective weight-loss program outside of the clinic. The current grant will be used to develop a new-generation scale for the mealtime feedback device that will be much less expensive to produce, has greatly improved portability, and can communicate wirelessly with smartphones.
Next Steps for HTAP Winners

The awardees are now working toward completing the development milestones that each team established with guidance from its von Liebig advisor. The timing and type of interactions between the grant winners and their von Liebig advisor vary according to the specific circumstances and the project’s stage of development. MBA student fellows from UC San Diego’s Rady School of Management have been assigned to three of the project winners to support the commercialization efforts through market research and business plan development. However, the end goal is the same: demonstrate POC and define a commercialization pathway.

Over the course of the year, awardees will conduct research to better define customer need and market opportunity, as well as to assess the competitive landscape. Drs. Chui and Jiang—neither of whom has publicly committed to a commercialization path—will also work with von Liebig advisors to review business models that appear relevant for the technology and to begin weighing the options of starting a company or seeking a licensee. Choosing a commercialization pathway can be a complex and difficult decision. Consequently, von Liebig will work with Drs. Chui and Jiang to consider issues and questions such as:

- Likelihood of securing patent protection
- Whether their invention is a platform technology or an incremental improvement
- Capital requirements
- Market dynamics
- Investor awareness or potential interest
- Potential interest in creating a startup around the technology
If a member of Chui or Jiang’s team wants to license the technology from his or her respective university and seek capital to start a company, von Liebig will work with the project teams to intensify focus on application targets, confirm the size of the market opportunity, and evaluate various gap-funding opportunities. Funding options might include applying for a Small Business Innovation Research (SBIR) contract or approaching early-stage investors through coordination with groups such as regional angel investment networks. von Liebig also will provide guidance on how to prepare for formal presentations to investors.

Drs. Leon and Ozcan, who have already formed companies around their projects and secured private seed capital, will pursue a different path forward based on their stage of development and commercial advancements to date.

Dr. Leon and his team will be working with guidance from von Liebig to complete software development and a scale prototype of the Mobile Mandometer®, with the objective of being ready for production at the end of the HTAP program period. If the team makes sufficient progress, von Liebig will also provide guidance on marketing strategy and make introductions to additional investors.

Dr. Ozcan’s invention, LUCAS, will follow a different path. Funds from the HTAP award will be used by the Ozcan Research Group at UCLA to develop the specific application of LUCAS for the point-of-care CBC testing outlined in the group’s HTAP proposal. At the same time, Dr. Ozcan’s new company, Holomic, LLC, will use private investment capital to further develop the LUCAS platform for additional applications of the core technology. von Liebig will work with Dr. Ozcan and the CEO of Holomic to conduct market and patient research required to fine-tune the business and marketing plans for the application of LUCAS for CBC testing.

Investor interest and early progress for awardees, such as Drs. Ozcan and Leon, is highly encouraging. The researchers’ ability to attract private capital demonstrates there is still a pool of investors willing to take on high-risk investments in cost-saving health technologies, even at the early-stage of development. With the addition of guidance from von Liebig and grant funding from HTAP sponsors, LUCAS and the Mobile Mandometer® have a good chance of surviving the commercialization process and delivering benefits to patients at a lower cost.

**Early Insights and Considerations**

As the HTAP awardees forge ahead, their stories will help illuminate the full impact of HTAP over time. Although the HTAP winning initiatives are still in an early stage, there are preliminary insights that can offer guidance for government, university, and commercial stakeholders who share the goal of accelerating commercialization of cost-saving health technologies.

**Changing Industry Dynamics.** Stakeholders should increase awareness among researchers about the implications of industry convergence and changing payment models.

As researchers investigate technologies with the potential to reduce healthcare cost, it is important to increase awareness about how convergence across the healthcare, life sciences, and telecommunications industries can affect development requirements and regulatory processes. For example, all but one of the HTAP awardees directly incorporated use of wireless technologies in their invention. As a result, they will need to anticipate mobile security and data transmission standards in addition to the US Food and Drug Administration approval processes for a typical medical device.
It is equally important for developers of early-stage health technologies to understand changing payment and business models. As the industry shifts toward more integrated and accountable models of care delivery, new health technologies will need to integrate with a range of health information technologies, including electronic health records. Researchers will also need to anticipate the importance of behavioral data generated outside of traditional care settings that helps to enable a more holistic view of the patient.

**Program Specialization.** *Funders and universities should consider the value of programs that target specific areas of need and opportunity.*

HTAP illustrates how a more generalized technology acceleration program model can be applied to the area of cost-saving health technologies. Analysis of HTAP submissions suggests that there is an opportunity for programs with an even greater degree of specialization. By establishing more targeted program objectives, funders and program facilitators can improve the odds of identifying breakthrough innovations in areas of critical need.

**Regional Program Models.** *Universities and funders of acceleration programs should consider the value of regional models and how unique requirements will affect program development.*

Multi-university models can offer significant value by reducing the cost of developing acceleration programs. They also foster ecosystems of support for researchers and entrepreneurs that extend beyond the contacts and resources of any single university. However, regional models may also create the need for new policies and processes. For HTAP, von Liebig established special agreements with participating universities to address the requirements of a multi-university program, including structuring grant payments in tranches based on development milestones.

**National Referral Network.** *Stakeholders should consider creating an actively managed national referral network that connects new technologies to funding, investment, and commercial opportunity.*

The four HTAP winners were not alone in submitting compelling research ideas. Broad programs, such as HTAP offer the benefit of attracting a diverse set of ideas across a large population of researchers. In most cases, however, total available funding falls short of what is necessary to support all worthy submissions. Some inventions may also miss the mark in a particular program, yet hold promise if evaluated against different criteria.

All stakeholders could benefit from a large-scale referral network for early-stage health technologies. An actively managed national network that engages universities, investors, and commercial leaders as partners would create additional opportunity for promising research to find funding and commercial pathways beyond the bounds of a single program.

**Commercial Insight.** *Industry should work more closely with universities and funders to establish stronger connectivity between academic research and defined commercial needs.*

One of the most important takeaways from HTAP thus far is the pressing need for stronger connections between commercial leaders and university research. When discoveries occur in the laboratory, most researchers are not responding to a specific market opportunity or considering the requirements for commercial success. The result is a high probability of misalignment and inefficiency as early-stage technologies attempt to find their way to market and industry seeks innovations. Commercial pathways may be even less clear in the case of cost-saving health technologies. With greater direction and defined commercial opportunities, entrepreneurs will be more inclined to help researchers develop their technologies, and the inventions will have better odds of success.
ENDNOTES


14. Booz Allen Hamilton analysis
19. Ibid.
23. Ibid.
29. Ibid.
30. von Liebig Center analysis of HTAP applications. In some cases, closer examination of submissions indicated that improvements in quality or access may risk short-term increases in cost.