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THE FOGARTY INSTITUTE FOR INNOVATION: A Device Incubator For Difficult Times

Nestled on the campus of community hospital El Camino Hospital, the Fogarty Institute might just be what a struggling device start-up community needs.

BY DAVID CASSAK

■ Buffeted by a difficult regulatory climate, a skittish venture capital community, and an increasingly bureaucratic research climate, the US medical device start-up community is facing unprecedented strains.

■ Six years ago, the renowned physician/entrepreneur Tom Fogarty established the Fogarty Institute for Innovation in offices at El Camino Hospital specifically to address some of the challenges that medical device start-ups face in today's climate.

■ To date, the Institute has started or nurtured five companies, one of which, HeartFlow, recently won the EuroPCR's prestigious Innovator's Award, and earlier this year added programs to do clinical trials and research, and education.

■ As it moves forward, the challenge for the Institute is sustainability – creating something that builds on the special talents of Fogarty and incorporates it into something larger.

Executive Summary >> TK

By any measure, the medical device industry should be the pride of US commerce. Few other industries have been as creative or innovative in bringing new technology to the fore – technology that offers tremendous benefits to society in prolonging lives and improving quality of life. And unlike other industries, the medical device industry, globally considered, is largely a US phenomenon, with a disproportionate number of players, both large and small, US-based.

So why then is the industry in such a funk – particularly the medtech start-up community that is the source of so much innovation? Indeed, go to any gathering of medical device start-up CEOs and their investors, and beneath a veneer of passionate intensity about individual technology lie concern, anxiety, and in some cases, real pessimism. Central to the debate: is the device innovation model broken?

The anxiety and concern isn't about the value or viability of the technology per se, but rather about a series of external forces that individually and collectively have made the push of innovative devices out of the lab increasingly challenging. A regulatory process that has gone from simple and straightforward to unreceptive and unpredictable, a venture financing climate that has grown skittish about the viability of device investing, and an academic research community that, wrestling with its own demons, has become overly bureaucratic – all of which has many device entrepreneurs and innovators worried that bringing forth

innovative devices is becoming increasingly difficult if not impossible.

If even seasoned executives are feeling frustrated, imagine how less experienced and first-time entrepreneurs feel. Six years ago, one of the most celebrated device entrepreneurs, Tom Fogarty, MD, working with officials at El Camino Hospital in Mountain View, CA, an independent community hospital located in the heart of the San Francisco device community, launched the Fogarty Institute for Innovation, an initiative designed to help the earliest-stage companies ramp up technology development quickly and efficiently in an effort to minimize, if not eliminate the external challenges.

Fogarty is himself an innovator and entrepreneur of near-legendary stature and brings enormous value and credibility to the Institute, but the really interesting piece is El Camino Hospital. Though it sits in the shadow of leading academic research institutions nearby, including **Stanford University** and the **University of California, San Francisco (UCSF)**, El Camino's status as a community hospital makes it a valuable partner, say Institute executives, bringing both an informality that is in striking contrast to the increasing bureaucracy of large academic research centers and a passion for innovation born of a number of thought-leading physicians affiliated with the hospital.

To date, the Institute has served largely as an incubator or accelerator of new technologies and companies. Earlier this year, it brought on a team of senior executives and

launched two new programs, one focused on clinical trials and research, the other on education, in order to give greater breadth and depth to the Institute's offerings. By itself, the Institute isn't likely to solve all that ails the venture-backed device community, but it at least points to a promising alternative to a model that seems to be running out of steam.

CHALLENGING TIMES

The Fogarty Institute for Innovation (FI) was founded five years ago. At the time, El Camino Hospital "had this idea that we would bring in Dr. Fogarty and create a non-profit environment to attract innovators and help them get their ideas through development and commercialization," says Institute president and CEO Ann Fyfe. "Because with everything that's going on at the FDA and in the venture community today, it's become very hard" to develop new technology.

And it's not just challenges in Washington and on Sand Hill Road, but those within the academic and clinical community as well. New rules and restrictions at leading academic centers around the country have made the transfer or translation of novel concepts out of basic research both more difficult and less rewarding for the physicians who develop them. Indeed, Fogarty himself has for the past several years been vocal about the difficulty of promoting innovative technologies within the large academic centers in the San Francisco area, particularly Stanford and UCSF, and the relative advantages of doing more in community hospital-like settings.

At El Camino, says Fyfe, physicians who "can't get things done at some other institutions can come here and we make it very easy for them to do their trials." Around 300 beds in size, El Camino is "one of the few hospitals in Northern California that is independent and not part of a large hospital," she goes on. And Fyfe notes that that size and independence has historically made the hospital something of a magnet for leading physicians, especially interventional cardiologists and surgeons like Frederick St. Goar, MD, Chris Zarins, MD, and James Joye, MD (who also serves as the Institute's chief medical officer) who see in El Camino "not only more freedom to practice medicine the way they want but also the opportunity to explore their ideas about innovation."

As noted, Tom Fogarty, a legendary innovator and entrepreneur who has won

just about every award possible in recognition of his contributions to medicine and device innovation, has long been frustrated by the new rules of tech transfer, and he didn't need much convincing to set up a program dedicated to innovation at an independent community hospital. In fact, Fogarty himself donated the first \$2.5 million to get the Institute going.

In effect, the Institute acts as a kind of incubator, helping physicians and entrepreneurs with little more than an idea by bringing resources to create fundable companies. Fogarty, who for years has run

Established as a not-for-profit organization, the Institute provides the companies with which it engages free work space and free mentoring, including help with everything from product design to access to seed stage capital and clinical thought leaders.

his own incubator, Fogarty Engineering, says the Institute doesn't replace that organization "but is modeled after it." Fogarty Engineering still exists, another vehicle by which Fogarty helps bring new companies to the fore, along with Emergent Medical Partners, a venture fund with which he is involved. But the Institute is different by design: it feels much more like an early research project group. Established as a not-for-profit organization, the Institute provides the companies with which it engages free work space and free mentoring, including help with everything from product design to access to seed stage capital and clinical thought leaders like Fogarty, St. Goar and Zarins, all of whom donate their time free of charge. For this early incubation, the Institute takes a small equity stake early on.

A START

Having occupied space on the El Camino campus since 2007, the Institute ran on a largely informal basis for its first three

or four years, tapping into the resources, both physical and clinical, of El Camino. This past January, the Institute moved to create something a bit more formal when it brought on two new senior executives, Ann Fyfe and COO Michael Needels, PhD.

A long-time hospital executive, with background in strategic planning, business and program development and marketing, Fyfe had known and worked with Fogarty for more than 20 years, dating back to their days at Stanford together. Mike Needels, a 20-year veteran of the biotechnology industry who has been a key contributor at multiple start-up and early-stage biotechnology companies, has extensive experience in the areas of life science technology creation, corporate operations, and scientific management. He was research director at Affymax Research Institute, research fellow at XenoPort Inc., and co-founder, and former president and CFO, of Nodality. Needels describes his new job at the Institute as a "jack-of-all-trades," involved in everything from identifying opportunities and writing long-term strategic plans, to creating a business strategy for the clinical research piece and putting in place medical benefits.

The Institute currently has three companies incubating: **Niveus Medical Inc.**, a spin-out from the Biodesign program at Stanford working on technology that prevents muscle deterioration in patients requiring an extended period of time in critical care, **PQ Bypass Inc.**, developers of novel technology used in peripheral vessel disease, and **Medical Sewing Solutions LLC**, which is producing a miniaturized sewing machine for use in laparoscopic surgery. In addition, **HeartFlow Inc.**, a company with an innovative non-invasive diagnostic cardiology technology designed to help interventionalists distinguish potentially problematic coronary obstructions from those that aren't problematic, spent some time at the Institute before exiting last year. (For more on HeartFlow, see "HeartFlow: Disrupting The Diagnostic Paradigm In Cardiology" this issue.)

Fogarty says there's no specific criterion used in selecting companies to be in the incubator – he notes that in his career he's started companies in a wide number of clinical areas and says of the Institute, "We'll look at anything." The most important criterion, he says, lies in whether the prospective company needs expertise that the Institute can bring to bear. "The number-one thing is, do we have some

expertise in-house and if not do we know someone who does," he goes on.

Fogarty says he tries to steer clear of new ideas where there might be a potential conflict with another company in the Institute. That aside, he goes on, "Basically, if it's a good idea and we understand it and have a pretty good idea of how to develop it, we'd be interested in it." Other considerations, he says, are, "Is it going to be so expensive, no one will use it? What's the market's size? And are we creating a new market or taking market share?"

AN INTIMATE RELATIONSHIP

To date, the Institute has selected a new company about once a year: HeartFlow in 2007, Niveus in 2009, Medical Sewing Solutions in 2010, and PQ Bypass in 2011. All of the companies have received some initial funding, some of it from Fogarty himself, others from angel investors, and in at least one case, PQ Bypass, the philanthropic dollars that have come into the Institute have led to a direct equity investment in the company. (HeartFlow is one of the companies that has actually raised venture financing.) And in a very real sense, part of what the Institute is trying to do is to find a way to create companies that sidestep, if not avoid altogether, a kind of development/funding crisis in medical devices that has left many even seasoned executives wondering whether a venture funding model that worked well just a half dozen years ago is broken. Indeed, while Institute officials regard as one of their strengths the relationships they have with VCs in the Bay Area – between Tom Fogarty and physicians like St. Goar, Joye, and Zarins, one would be hard pressed to find a VC who hasn't either invested in one of their companies or wanted to – they're also quick to point out that not all of the companies coming out of the Institute will eventually be funded by venture capital.

Ann Fyfe says that the Institute considered more than 70 ideas before selecting the four companies that currently reside there. Those who'd like to submit an idea to the Institute can do so through the company's web site. After an initial screening, which decides whether the idea should be taken further, a small advisory group within the Institute, made up of Fogarty and a team that includes local, seasoned entrepreneurs and clinicians familiar with the disease state, helps decide which projects to bring into the organi-

zation. Even if the Institute decides not to take on a project, Fogarty or another Institute official might send the entrepreneur or physician to one of their dozens of contacts to help refine the idea or some part of it – to shore up IP, for example, or resolve some clinical issues.

Interventional cardiologist Fred St. Goar himself has an impressive track record in bringing forward innovative technology – he worked early on at HeartPort and was the physician founder at Evalve – and has been deeply involved in the Institute's first project, HeartFlow. Having begun as a research project in the lab of Stanford professor Charles Taylor, MD, PhD, a pioneer in computational fluid dynamics with appointments in both the medical and engineering schools, HeartFlow did some early technology development with around \$15 million in grants from the US government, "trying to figure out pressure flow modeling of large vessels," St. Goar explains. Working under Chris Zarins, widely recognized for his work in AAAs and one of the thought leaders resident at El Camino, Taylor realized that there were broader applications. "As he advanced his understanding of physiologic modeling, he appreciated that he could apply this technology to the coronary arteries, which is a much more challenging problem in terms of flow demands, vascular resistance and oxygenation requirement," St. Goar explains.

But while clinicians like Zarins and St. Goar saw promise in Taylor's research, it wasn't clear to others where the opportunity was and whether the project warranted further work. "The issue was, he [i.e., Taylor] was trying to figure out how to apply the algorithms, wasn't quite sure, and hadn't made the jump into the coronary tree yet," St. Goar goes on. "It was quite apparent he didn't have the clinical support [at Stanford] that he needed and, in total transparency, he needed to be a step away from Stanford."

Ironically, Tom Fogarty himself wasn't quite sure what to make of HeartFlow in the beginning. "At first, I thought they were full of themselves and would never get it done," he recalls. But Fogarty had confidence in Taylor and Zarins and was willing to underwrite the project at the Institute. "As I watched, it started to make sense and I got very enthusiastic," he says. "But when they first got here, I thought we'd just be wasting space."

If there's a sweet spot for the Fogarty Institute, HeartFlow exemplifies it: a highly promising technology that physicians like

Fogarty, St. Goar and Zarins can see the potential for – or are willing to devote time and resources to until that potential becomes clearer. To be fair, St. Goar acknowledges that without a place like Stanford to provide the initial support and basic research opportunity, HeartFlow would likely never have gotten to the point where it came into the Institute. But just as certainly, having taken the basic research as far as he did, Taylor needed a different kind of outlet and the Institute provided it.

St. Goar calls HeartFlow "a marquee project" and "a great initial endeavor" for the Institute because it fits so neatly with the mission of the organization. "What we're trying to do here is to bridge this valley of death for these technologies, ideas that get started and need to get traction but can't make it over the chasm to commercialization." And what do you need to do that? "You need to be nimble and adaptive," he goes on, characteristics typical of incubators. "And you need to have an intimate back-and-forth relationship with your clinical community."

The Fogarty Institute has that, obviously. Just as important, being located on the campus of a community hospital like El Camino offers a kind of informal, responsive setting that is a huge plus, even in a geography filled with leading academic centers – it's basically a group of people passionate about medicine and technology and the intersection of the two, who spend a large portion of their day treating patients and working on ideas for new technology. "The Institute is right across the hall from Jim Joye's and my offices, and there are nine other cardiologists here," St. Goar goes on. "We're constantly back and forth across the hall." St. Goar's own experience is typical. He wasn't involved in HeartFlow while it was at Stanford. When the project came to the Institute, he was tapped to provide early advice on some of the clinical issues. Now St. Goar is one of HeartFlow's biggest supporters. "It's one of those ideas that when you get it, when the light bulb goes off," he says, "you realize this is going to change the playing field."

Indeed, St. Goar predicts that HeartFlow "will have a dramatic impact on cardiovascular care" and "has the potential for growth comparable to some of the Silicon Valley social media companies." (The company won the Innovator's Award at this year's EuroPCR meeting.) But that wasn't always obvious with HeartFlow. St. Goar is being more than a bit modest when he

says that what the Institute and El Camino provided early on was “the space, the flexibility, and access to people.” What it really provided was a group of key thought leaders able to grasp the kernel of the idea and willing to work at the project until something came of it. Of HeartFlow’s early days in the Institute, St. Goar says, “They had their servers and they took office space, but they were still trying to figure out how to commercialize the opportunity, how to turn it into a real business.” (In fact, HeartFlow has already done both a \$2 million Series A, largely from its founder, and a \$20 million Series B, with investments from US Venture Partners and Capricorn came in 2010.) And at a time when the venture community is struggling to find value in novel device technologies and, hand in hand, the regulatory process is giving both investors and entrepreneurs pause, the kind of bridging that the Institute provides to early-stage projects like HeartFlow and Niveus is more than helpful – it may mean the difference between a project that never gets out of the lab and one that does. “Could we have done this at Stanford?” St. Goar asks. “Maybe. But things happen so much more quickly here; there’s flexibility and access to the clinical and entrepreneurial communities.”

JOINING THE INSTITUTE

All of the companies that have come through the Institute to date have followed somewhat different paths, but Niveus may be representative if not entirely typical of how the Institute works.

CEO Brian Fahey, PhD, was a fellow in Stanford’s Biodesign program where, three years ago, he won a \$10,000 prize for the best business plan. Soon after founding the company in July of 2008, he approached Tom Fogarty to talk about his idea. “I worked with him early on when he was just thinking through the concept,” Fogarty recalls. “Intermittently, he’d call or come over, and it pretty soon got to the point where I saw that he had something that would be helpful.” By January 2009, Fogarty had put in the first angel investment, of \$50,000, and invited Fahey to launch Niveus within the Institute.

Fahey himself says that Niveus “was really more of a shell company” for the first six or seven months after its launch. “The idea was well-vetted, but it needed more time behind it,” he says. Fahey was at the time consulting for three other medical device start-ups while trying to get Niveus off the ground. When, after making his investment, Fogarty invited Niveus to join the Institute, Fahey was interested, but unsure. (Fogarty’s angel investment wasn’t contingent upon Niveus becoming part of the Institute.) After presenting to the Institute board, however, says Fahey, “It was immediately clear that this was a great opportunity for Niveus,” says Fahey.

Niveus is developing a muscle stimulation technology to prevent deterioration for patients who have to spend a lot of time in critical care. Muscle stimulation is used often in Europe for people in rehab, but there are critical issues in extending its reach, most notably factors related to

the unique comorbidities of patients in US ICUs. Niveus’ goal is to provide technology to overcome these critical issues. Says Fred St. Goar, “There are patients who get into an ICU setting and basically melt because they’ve had no stimulation. Take an athlete and put them to bed for four or five days and they come out deconditioned. Someone in their 70s or 80 who’s in the ICU for a week or two basically turns to mush.” Niveus nicely fits the profile of technologies the Institute is looking for: it has both a tremendous patient benefit and the potential to save the health care system money.

Supported by Fogarty’s initial angel investment, the Institute provided an important boost for Niveus; the \$50,000 combined with the free access to equipment and facilities allowed Fahey to end his consulting relationships and concentrate all of his attention on Niveus. “Looking back, it seems crazy that we’d make a decision based on \$15-20,000 worth of equipment and office space, but at the time it was critical money and they had all of the equipment that we needed,” says Fahey. The \$15-20,000 was given free to Niveus, meaning that the company’s initial \$50,000 investment could stretch even further. “I saw it as an opportunity to give up a little bit of equity that, frankly, wasn’t worth all that much at the time and to drive [development] quickly at a very capital-efficient rate,” he says.

Fahey says Niveus is now “at a turning point,” having just raised its Series A round, in two tranches, of between \$1.5-2 million

Exhibit 1

Fogarty Institute Companies

COMPANY	TECHNOLOGY	TERM	STATUS
Heart Flow	Patient-specific, mathematical models of coronary blood flow for non-invasive stenosis detection.	10/07-6/10	<ul style="list-style-type: none"> Received \$14M VC investment. 40 jobs created.
Niveus Medical	Novel devices for preventing muscle deterioration in patients requiring extended periods of critical care.	2/09-present	<ul style="list-style-type: none"> Received first funding. Final prototype testing.
Medical Sewing Solutions	Miniaturized sewing machine for use in laproscopic surgery.	2/10-present	<ul style="list-style-type: none"> Final prototype development ongoing.
PQ Bypass Inc.	Novel devices for thepercutaneous treatment of peripheral vascular disease.	1/11-present	<ul style="list-style-type: none"> Received \$1M angel investment. Prototype development ongoing.

SOURCE: Fogarty Institute

from a number of angel investors, including Life Science Angels, and a couple of small venture firms. The company is likely to stay at the Institute for the next nine to twelve months – Niveus' hiring plans are modest, Fahey explains, and so the company doesn't necessarily need a lot of space, and it has some clinical trials going on at El Camino. Niveus is likely to stay at the Institute, in exchange for a small increase in the Institute's equity stake in the company, through the end of its Series A funding.

But the Institute's support has been invaluable: the company has burned through only around \$250,000 in two and a half years, during which time Niveus has been able to develop and refine its core technology, do all of its prototypes, file four patents, and gather clinical data on more than 80 patients. "We were able to get the connections and resources to run extremely efficiently" from a capital perspective, says Fahey. Even more, he goes on, "we would never have gotten the financing of our Series A if we didn't have the relationship with the Institute."

A HALO EFFECT

Niveus seems, in many respects, a classic incubator story, allowing a first-time entrepreneur to realize his vision by providing a wide range of support services, perhaps most importantly, mentoring and advice from experienced executives. But it isn't necessarily typical of the Institute: PQ Bypass has already raised \$1 million in venture capital money and has recruited a seasoned CEO, Richard Lotti, and has folks like Jim Joye and Richard Ferrari, a principal with De Novo Ventures and long-time industry executive, on its board. That suggests a role for the Institute not just with first-time entrepreneurs but with more seasoned executives as well.

As noted, the specific resources available from the Institute – from office space to prototyping equipment to advice from thought leaders – has been extremely valuable for a company like Niveus. But Fahey notes that "the bigger piece of the puzzle that has made this successful for us is the proximity to and relationships with El Camino Hospital." He calls El Camino "a very forward-thinking hospital" and points specifically to Niveus' experience with its IRB as an example. "The IRB is very friendly, and the process is very straightforward and clear," says Fahey. "I've now had IRBs at three different institutions and this was by far the easiest." El Camino was,

he goes on, "very reasonable; what really sets them apart is there's a very clear line of communication. There's no guessing what the IRB might want to know with the risk that you have to go through another review cycle if you guessed wrong."

The relationship between the Fogarty Institute and El Camino Hospital is strictly arm's length, though El Camino provides office space and access to some facilities virtually for free in exchange for the bragging rights associated with a device incubator branded with Fogarty's name. And while there is, otherwise, no formal affiliation, what affiliation there is has significant value for the hospital: located just minutes from Stanford and within shouting distance of UCSF, the Institute is part of a broader initiative on the part of a small, independent facility, with a focus on cardiovascular and oncology care, to distinguish itself. Says Ann Fyfe, "[Hospital officials] love having the Fogarty Institute on campus because it really attracts physicians with great ideas and helps the physicians here bring their ideas forward. There's a halo effect in being able to say that they have the Fogarty Institute on their campus."

Indeed, many innovative technologies have done early research and/or clinical trials at El Camino in the past – CoreValve's percutaneous valve, for one – but the hospital has been overshadowed by its larger academic neighbors. Even people with long experience in the medical technology industry tend automatically to associate innovative devices with Stanford and UCSF, overlooking the role of facilities like El Camino. An affiliation with the Fogarty Institute not only gives the hospital a more direct link to innovative technology as it emerges from the clinic, but has also helped to raise the hospital's profile as a center of innovation. Stressing innovation and independence, El Camino would like to position itself as "the hospital of Silicon Valley," as Fyfe puts it, and an association, even if informal, with the Fogarty Institute "is invaluable," she says.

Company creation or incubation is, in fact, only one of three pillars upon which the Institute is built. As part of its broader initiative to expand its reach, the Institute launched two new programs, one focused on clinical trials and clinical research, the other on education, the former funded by a \$4 million gift from Edward and Pamela Taft. Since the incubator can really handle only about four companies at a time, the research and education programs help to

round out and make more robust the work the Institute is doing.

The clinical research program is designed to offer clinical trial management services both to companies within the Institute, providing early validation for FII technologies, and also to companies outside the Institute. It also provides FII innovators with a physician advisory network and, because of El Camino's status as a community hospital, offers clinical research services at a lower cost than those available from academic centers, through what Institute executives call "a streamlined, nimble, and efficient operational structure."

The Taft gift has helped the new research program get up to speed quickly – under the program, the hospital is already conducting some 20 clinical trials. And the special nature of the Institute and its collaboration with El Camino gives the clinical research initiative a novel spin. Notes Tom Fogarty, "There are a lot of people at this hospital who really want to be involved in innovation." Nurses, as much as the thought-leading physicians, "are very enthusiastic," he goes on, in contrast to academic medical centers where the front-line staff on the trials often feel a burden "because they're busy and over-stressed with bureaucratic obligations." At those facilities, says Fogarty, clinical trials "are a huge pain. Everyone has gotten tired of clinical studies. Here, they get excited."

Broader in scope than the other two pillars, Fyfe likens the education program to a think tank dedicated to device innovation. The program will embrace a number of initiatives, offering post-graduate fellowships as well as events such as workshops, symposia, and roundtable discussions on key topics in medical innovation. Institute executives see the educational piece in particular as a "vehicle to support the broader [medtech] innovation community," in anticipation that these educational activities "will catalyze the commercialization of important medical innovations." The Institute's goal is to use the educational program to reach a much larger audience than it can through the incubation and research programs alone, "engaging and inspiring groups, such as college and high school students" interested in device innovation.

Eric Pifer, MD, is an internal medicine physician and the chief medical officer of El Camino. "El Camino has always prided itself on being more than a traditional

community hospital," he says. Most community hospitals are almost exclusively focused on patient care and the patient experience - on "having a warm friendly patient experience for people in the community," Pifer goes on. El Camino, by contrast, sees its core culture differently. "Because we're in Silicon Valley, we're right in the heart of where all of the companies that are providing the most innovative technologies in the world are located," he says.

Indeed, within ten miles of El Camino Hospital are the world headquarters of Google, Apple, and Intel, to name just three. And that, says Pifer, "creates a culture in our community that focuses on entrepreneurship." As a result, El Camino executives, too, like to think of themselves as steeped in an entrepreneurial and innovative culture. Says Pifer, "We pride ourselves on being one of the most creative and innovative hospitals in the country if not the world." And the relationship between El Camino and the Institute both fulfills and builds on that, creating what Pifer calls "a much greater ability for the hospital to attract and participate in projects that will drive innovation and creativity and new technology adoption in health care."

On its own, El Camino would, it's hoped, foster a culture of innovation. But the Institute helps, says Pifer because "it attracts the kinds of people" who exemplify that

culture. El Camino's thought leaders reside mostly in the interventional cardiology and cardiac surgery practices, but the hospital is also strong in cancer care and oncology and some surgical specialties.

Cultural impact and branding aside, there are tangible benefits to El Camino - the opportunity to do clinical trials that comes through the Institute being a major benefit. Indeed, Pifer notes that five years ago, notwithstanding the culture of innovation and entrepreneurship at El Camino, there were people at the hospital who didn't quite get what the Institute does and the benefits that might accrue. "There's been a learning phase for a lot of people who were part of a more traditional hospital setting," he says. "They didn't get it at first." But as the relationship has deepened, "we're seeing a much greater understanding of what something like the Fogarty Institute can mean [to El Camino Hospital] and where the advantages of an affiliation lie."

IS THIS SUSTAINABLE?

As with all incubators, the challenge for the Institute won't so much be to nurture companies with innovative technologies, but rather to nurture the Institute itself - to create a sustainable entity that can continue to develop companies on a larger scale and well into the future. By himself, Tom Fogarty would likely launch a number of new companies over the next several

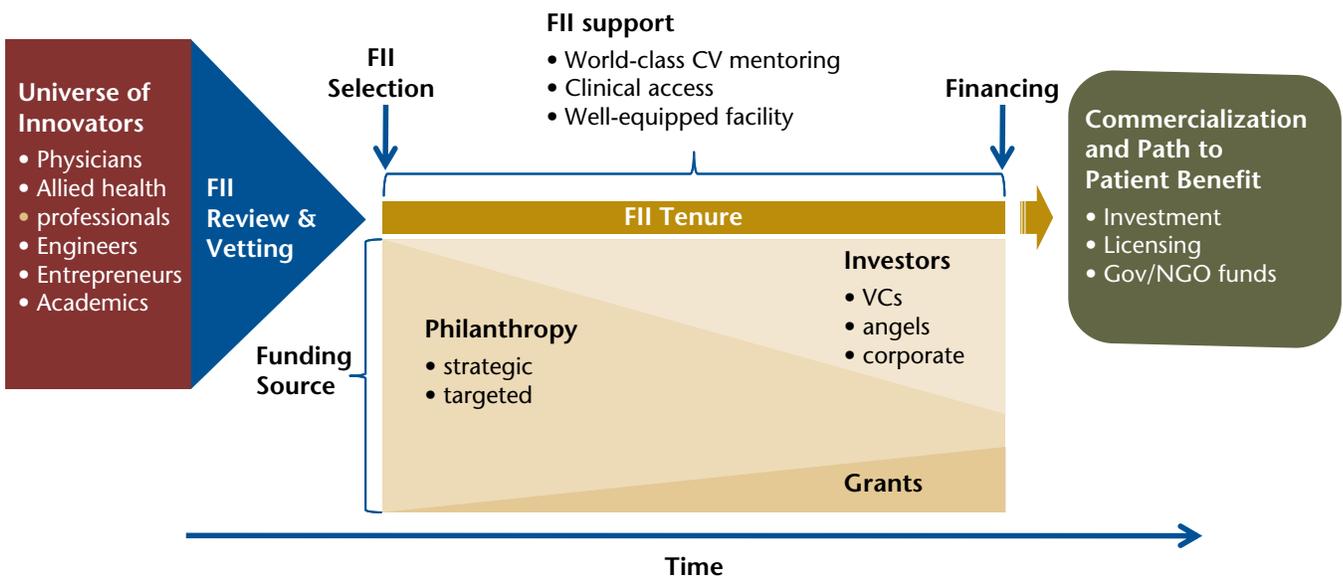
years - he's been doing it for more than 40 years. And much the same can be said for physicians like Fred St. Goar and Jim Joye - there's little question that, even without the Institute, they'd continue to develop ideas for new technology.

What the Institute offers is a refreshing context that begins to alleviate some of the more difficult aspects of technology development today. Fogarty and the physicians at El Camino Hospital appreciate both the collegiality and informality of the Institute - especially after having worked through some of the more restrictive processes associated with larger hospitals and academic centers. But that informality has its limitations as well. Ann Fyfe notes that in the past, Fogarty's mail box would overflow with people wanting to bring ideas into the Institute, "and we had no real process for getting back to folks or for bringing in the best ideas." In part, the decision to bring on a CEO and COO last January was made because, she says, "there'd been a little bit of an *ad hoc* feeling" to the activities of the Institute in its first several years. "We needed more of a structure to get things done."

That's not to say that those affiliated with the Institute aren't happy with the progress made today. In particular, FII officials have high hopes for HeartFlow, which they believe will not only be a valuable technology in its own right, but will, as a first effort, testify to the capabilities

Exhibit 2

Innovator Support Process And Funding Vehicles



SOURCE: Fogarty Institute

of the Institute. Still, those affiliated with the Institute wanted on some level to create something more self-sustaining. Thus, one major challenge the Institute faces is, ironically, becoming at once more than and less than the Fogarty Institute.

It's the challenge faced by all incubators founded by strong, creative individuals: finding a vision and sustainability beyond a single leader. For now, the Institute's greatest strength is the ability to leverage

more companies. "I think the board and Dr. Fogarty decided it was time to bring in people like Mike [Needels] and me and try to take this to the next level," says Fyfe, "to see what we can really do with this."

Part of the financing challenge lies in the nature of incubators themselves. Very much like venture investors – perhaps even more so because they don't take management fees and start companies even before their first institutional round – incubators often

Having launched four companies in as many years, it's not likely that, even with the addition of more professional staff, the Institute will be able to accelerate the pace of company creation. Fyfe notes that the Institute is looking to broaden its impact by expanding its capacity. Indeed, just as incubators themselves work on the principle of leveraging capabilities, the Institute itself is looking to reach out and find partners to bring in additional capabilities. Fyfe notes that she and Mike Needels spend part of their time "looking for other partners, people who are doing things similar to what we're doing and to whom we can turn to expand our capacity and run some of our programs through." Fogarty and others affiliated with the Institute have long-standing relationships with Stanford's Biodesign program, which is where Niveus got its start, and they've begun to hold talks with other, for-profit incubators.

The different paths taken by Niveus and PQ Bypass suggests that the Fogarty Institute can accommodate a number of different models, which in itself speaks to its sustainability.

the talents and presence of Tom Fogarty and the thought leaders affiliated with El Camino Hospital. Indeed, Niveus' Brian Fahey went first to Tom Fogarty for advice before he ever pitched Niveus to the Institute board or received the company's initial angel investment. "I really went to him more for advice than anything else," says Fahey. "I wasn't necessarily expecting an investment."

That's not at all unusual in device development, particularly at the level of incubation because the ideas at that point are often ill-formed, unclear, or perhaps just headed on the wrong path. Fogarty's insights into a very-early-stage project are invaluable to a physician or entrepreneur and may mean the difference between getting quickly to something viable and heading down a sinkhole. Fred St. Goar recalls that the first Evalve concept was "primitive, at best." But the company was able to attract investors because "they were investing in a concept and in people," he says. "They had the confidence that the Evalve team knew how to get it done. The team may not have been able to visualize the road to clinical application, but the investors had the confidence that they could."

BEYOND ANGEL INVESTORS

And then there are the financial challenges any incubator faces. Prior to January, the Institute was largely dependent on Tom Fogarty for funding; bringing on a team of senior executives has helped not just to refine the processes and make the Institute less dependent on Fogarty, but will also help raise the capital to launch

find themselves cash-strapped: they invest a lot of time and money in a company just to make certain a company's technology is viable, but then must wait for an exit before they can recoup any investment. And the Institute, though non-profit, shares many of the financing pressures that other, for-profit incubators face.

To date, the companies within the Institute have relied largely on angel investment, though Fogarty's connections within the medical device community should ease outreach to venture investors, as well as to angel groups and even corporate partners. And Institute officials expect that those who contribute philanthropically may even in some if not all cases become angel investors in the companies that come out of the incubator.

Still, the Institute's not-for-profit status informs the financing issue a bit: as Mike Needels points out, the Institute will be able to draw on some philanthropy but in looking for non-philanthropic sources of revenue, will have to do so with financing models "in complete alignment with our non-profit mission, which is to benefit patients by supporting medical innovation."

Ann Fyfe notes that the clinical trials and research programs will help provide some additional funding for the Institute, and there's always the equity stakes it takes in its companies. But, as she says, "we have to wait to see if these companies make it, and that could be five years or more. Who knows?" The Institute still hopes to get some funding from philanthropic sources, she goes on, "but we wanted a business model that will help us more."

A DIFFERENT KIND OF INCUBATOR

The challenge for the Fogarty Institute isn't to replace or move beyond the talents, insights and connections that Tom Fogarty brings, but to build on them and to incorporate them into something that is larger than any one individual – even if that individual is Tom Fogarty.

The different paths taken by Niveus and PQ Bypass suggests that the Fogarty Institute can accommodate a number of different models, which in itself speaks to its sustainability. Asked if, after making Niveus a success, he would bring a second company into the Institute, Brian Fahey says yes under the right circumstances. "It depends on the project," he says. "If you have the kind of company or technology that could see a huge uptick in value as the result of a capital efficient model, then it makes a lot of sense."

Fahey notes that if there's an issue with the Institute it's that Tom Fogarty and the other physicians involved "are so prestigious and have been so wildly successful, they can sometimes lose touch" with the typical incubator candidate: a young entrepreneur who has neither previous success nor extensive connections in the medtech community.

Though a large part of what they do lies in launching and nurturing companies, ILL executives aren't entirely comfortable with the label of incubator. "We struggle with it [i.e., the term]," says Fyfe. "We haven't yet figured out what to call it."

And Mike Needels notes that because of its non-profit status, the Institute has a different mission than other, for-profit incubators. “Obviously, if we’re going to get our technology into the hands of patients, that means we’re commercializing it and so somebody’s going to make some money off of it,” he says. “But our primary criterion for selection isn’t ROI, it’s patient benefit.”

More to the point, Needels notes that the Institute also forms a somewhat different relationship with its companies than, say, an incubator like The Foundry. While the Institute values its equity stake, it is likely to be somewhat less proprietary about the companies it launches. The Institute will be an important nurturing influence, but companies are less likely to be identified as FII companies the way companies coming out of, say, The Foundry or The Innovation Factory are. “With most incubators, you, as a founder, have to give up a lot when you become part of them,” says Needels. “We want to give the innovators as much [equity] as we can to hold on to. It’s a totally different paradigm.”

Brian Fahey’s experience is illustrative. Fahey spoke with a number of other incubators before becoming part of the Institute but found that most incubators “are quite frankly not built for founders who want to run to run the company themselves. They’re really looking for ideas they can hand over to the expert team they already have in house and then that in-house team can then run with it.” For those incubators, an equity stake of

closer to 40%-60% may be justified because the incubator itself will do so much of the technology development and company creation; for the most part, what the founders provide is the idea behind the technology. “The model of the Fogarty Institute was very different,” Fahey says.

At least in Niveus’ case, the Institute provided a number of important resources, but basically left Fahey alone to run his company. Fahey says he doesn’t know if his experience is typical. “I’ve been able to do more autonomously than most first-time entrepreneurs might be able to expect,” he says, in part because of his Biodesign training. Still, he adds, Niveus operates “as an independent entity” within the Fogarty Institute. “They don’t pressure me or structure me to do things in a certain way,” he goes on. “They’re there for advice and mentoring and connections when I need them and ask for them. But for the most part, they stay out of my hair and let me run my company.”

In fact, Mike Needels argues that the Institute could even become a feeder for other incubators, helping to advance technology further and, in the process, by reducing risk, ease a financing model that for many in the medical device start-up community is strained today, if not outright broken.

Indeed, if the current venture model in devices isn’t quite dead, says Tom Fogarty, “It’s in the ICU,” with too many obstacles, too many reasons for key players along the way – inventors, entrepreneurs, investors, and regulators – to say no. That’s

where the Institute comes in: to create a vehicle to remove those obstacles early on in the process. Fogarty himself, who has helped to found so many companies, both as product designer, entrepreneur, and, more informally, advisor, has never particularly liked the notion of an incubator. “It’s an inappropriate term,” he says. With an incubator, you put an egg in and after a set period of time, a chicken comes out. With medical devices, he continues, “When you innovate, you don’t really know what’s going to happen or when. Sometimes it happens way before you expect, sometimes much later. There’s no sense of predictability with real innovation.” Even more the reason the Institute will likely play a valued role in creating important new medical devices going forward.



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