Stanford eCorner

Implementing Ideas into Practice

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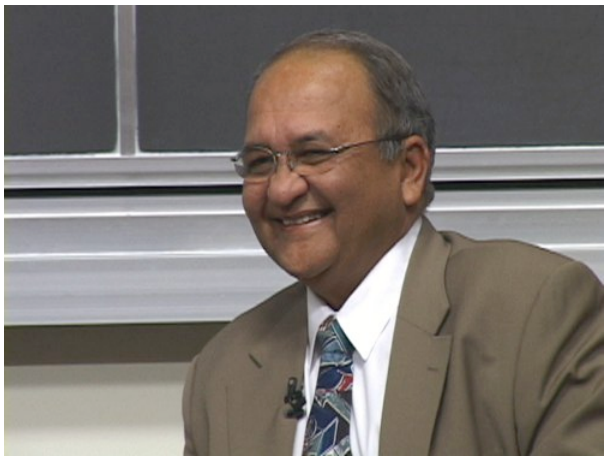
A good idea is a start, but sometimes an entire market has to be created for both the common good and for a new product's longevity. Here, InCube Labs CEO Mir Imran, an established veteran of entrepreneurial pursuits in medical devices, outlines how he both identified a medical problem and developed a solution - and how he put forth the resources necessary to prove to the national medical community that his product could help save lives.



Transcript

I think ideas are so easy to come up with. They're the easiest thing. It's the implementation and it's a long road. Whenever you launch a company, it's a six- or seven-year journey if you're successful. I spent a lot of time early, and I'm willing to kill these ideas if they don't meet the criteria. So why don't you tell us a little story? I want to hear about at least the process that typically happens and maybe the timeframe for one of these ideas. Let's take one that's a success from idea to actually some exit and the hurdles along the way. These ideas come in random and multiple ways. So back in 1992, a friend of mine had a carotid endarterectomy, which is a cleaning up of carotid arteries, and ended up with a stroke, and he had then a few months later, the second carotid artery cleaned and he had another stroke. I started scratching my head and I said, "These are embolic events and there should be a way to fix that or prevent that from happening." I was busy with a couple of other companies so it was in the back of my mind.

Then, another year later, another acquaintance of mine had a saphenous vein graft angioplasty and ended up dying because of a huge amount of embolic load flowing downstream into the heart. So that really was the beginning of the concept. So I said, "This is a problem that's worth fixing." So I went to some of my friends who were interventional cardiologists, folks here and at other institutions. I said, "Is this a problem in your practice?" They said, "No, we never have embolic events when we're doing stenting or angioplasty." So I started looking at literature and what I found, sure enough, in the U.S., clinical literature, back in the early -90s, couldn't find any papers talking about embolic events and complications, but Europeans were writing about it. They're not worried about getting sued. Always, when you're looking at some unique problems, look at European literature. Sometimes, they're much more open about problems. So I decided to come up with some tools that prevent embolic events during the procedure. It wasn't really an uphill battle because when I went to talk to investors, in doing the diligence, they would call these same guys who said this is not a problem. So I told them that, "This is what you're going to hear, but trust me." I think primarily because I had established a long track record so the investors said, "Fine." In the presence of clinical experts saying, "No, we don't need it," I was able to raise four or five million dollars and launched the company.

As we started getting some clinical data, publishing that data, there were 20 other embolic prevention companies that came out because everybody saw how important this area was. What we found out was in saphenous vein graft therapy or interventions, there was almost a 20% incidence of embolic events. It was huge. So we were able to do a randomized trial. Here's another interesting anecdote. We got FDA approval on a 510(k). Most of you know what a 510(k) is. I think a lot of people won't know what that is. 510(k) is a faster way of getting FDA approval, and it applies to those devices that have a precedent. So if you have a device that is similar to some other device and it is not going to cause any harm to the patient, you

have to come up with justifications, and FDA generally gives you a very quick approval.

So we got that, but we realized that if we were to start selling the product with that approval, physicians, they were of a mindset that embolic events were not a problem. So we went back to the FDA and said, "We would like to do a randomized trial under a PMA." PMA is the longer protracted thing, and we wanted to establish scientifically in a randomized trial with statistical significance that we can reduce embolic events, and it does make a difference to the patients. It took another $10 million and two more years to do 800 patients. That helped turn this approach into a standard of care. So physicians could no longer say, 'We don't need it." Very interesting. So we ended up selling the company to Medtronic.