Managing Expectations in Medical Device Development, Part 1

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Around 15 years ago, I was fortunate enough to study for a Ph.D. with an Entrepreneurial Professor. Five years later, after working on a few healthcare-related projects, we were then fortunate enough to snag an ambitious MBA graduate with an executive retail background, looking for a new challenge, and gained support of doctors. This was essential, as no-one invests in a two-man professor and engineer—only CEOs and doctors.

So we set-up a company, wrote a business plan, and naïvely began attending investor conferences. Many pitches later, we secured seed funding, and very many pitches later, series A funding to develop a novel medical device technology.

The business proposition was for a new application of an existing technology that had never been applied before to that particular patient group, so there were significant development unknowns. However, using various philanthropic and University Challenge seed funding, we had a proof of principle prototype, positive clinical data from almost 100 patients, and a business case that sounded reasonable so felt we were on the verge of commercial success!

Part 1 of this blog article describes issues faced during development; Part 2 will

describe issues faced with investors [1].

University Proof of Concept Prototypes vs. Robust Medical Devices

Seed funding allowed us to develop a proof of principle prototype and get the results necessary for Series A funding. With the professional investor money, we then had to build a product, and build a proper medical device company to go with it.

The phrase “fail fast” is sometimes used with technology start-ups, but because at the time we felt we were close to commercial success, we didn’t want to convey the negativity associated with those companies who build seemingly endless prototypes, burning through cash but never actually getting to market. The proof of principle was a university style “works like” prototype that worked fine with a graduate at the helm during clinical study with off-line analysis.

As it turned out, we didn’t fully understand several critical parameters (such as how robust it actually needed to be), but management was disinclined to undertake any retrospective work before starting actual new product development productization because we felt we were “almost there” and didn’t want to waste time—something I have seen from several research groups since. So our way of reducing development risk was to reuse technology elements from the proof of principle prototype, which was actually designed with hand-wavey assumptions and finger in the air first approximations. We knew the test had to give results quickly, but didn’t do any field studies of how actual clinical users might use the device.

Unfortunately, the clinical study results that came back were not commercially viable, in part due to the way untrained operators used the sensor versus how we used the sensors in the lab. This resulted in uncomfortable discussions with the investors and the need for subsequent redevelopment. The overall cost for development was more than double the original development budget, but more importantly, extra development time burned through more cash with company overheads and lost opportunities.

Things to do Differently

Will Smith once said “I'm a guy. Since when do we get anything right the first time?” While that might work for the Fresh Prince, I don’t think it would have helped with the investors.

First, delays in development can hugely affect a start-ups ability to execute. One example of a lost opportunity was caused by delays in actually starting clinical study when the clinical team were ready to go. Clinical staff are usually pretty busy with plenty of other opportunities available, which resulted in a quick three month validation study taking nine months. So in addition to the cash burn caused by redevelopment, delays in starting clinical study caused further delays.

Second, as this was not a better mousetrap project (where all critical parameters have been already well established) and we were inexperienced in medical device development, we should have performed a detailed design review with experienced medical device developers, then decided what could be optimized based on

acceptable risk. A formal product definition framework [2] would have forced us to ask that question explicitly.

In Closing

Reducing risk has a cost, but unanticipated cash burn due to clinical/redevelopment delays and lost opportunities has a bigger cost. As Henry Longfellow said, “It takes less time to do a thing right than it does to explain why you did it wrong.”

Links:
[1] http://www.mdtmag.com/blogs/2013/06/managing-expectations-medical-device-development-part-2
[2] http://starfishmedical.com/services/product-definition/