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Medtech Innovators Must Find The Right Problems To Solve

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More Money Is Available For Early-Stage Medtech Projects

Executive Summary

In the world of medtech innovation, investment and market access, commentators are seeing a maturing attitude to risk, more readiness to address workflows and greater awareness of being on the ball in a regulatory sense. Senior executives from consultancy firm Technology Commercialization Group (TCG) give In Vivo their take on what is behind these changes.

- Early-stage funding for medtech companies is becoming more common than it has been in recent years, and is coming from a wider variety of investors and funders, pointing to a greater level of investor sophistication.
- Regulatory compliance is ever a challenge but gaining higher priority for medtechs that are securing reimbursement and insurance coverage, and developing reliable business models – particularly in ehealth, digital health and mobile health.
- So what? Companies increasingly understand the operational aspects of their product or service, which not only helps to de-risk early investment, but shows they know where it fits in the clinical workflow, that it solves a clinical problem and delivers economic value.

It is often hard to be heard above the general hubbub of medtech business in action – the soundtrack to the annual Medica event – anywhere in the vast Düsseldorf exhibition arena. But over at the North Carolina stand at Medica 2018, the Technology Commercialization Group's take on current realities and future trends in global medtech adoption were coming over clear as a bell.

TCG executives Dean Gray and Reinhard Merz, along with Russ King, president of TCG partner company Methodsense Inc., were in agreement that there seems to be more money available for early-stage projects. Gray said, "From what I have seen over the couple of years in the US, money for early- and growth-stage companies is coming not just from traditional venture capital or private equity sources, but also from angel investors, family offices and recently Asia."

In addition, capital medical equipment companies, which are always challenged when trying to attract investment (most investors are challenged by capital goods business models) are also getting more attention from family-owned investment offices in the US, which are showing increasing levels of investor sophistication. "They are making more investments at early stages, which is very encouraging for these capital equipment companies," said Gray, who is focused on medical devices, diagnostic imaging and digital health.

Why is this change evident? There are more sources of early-stage funding than there were five or 10 years ago. Angel groups are more prevalent in medtech, and non-dilutive funding has become a bigger source for start-ups. These include the National Institutes of Health's Small Business Innovation Research (SBIR) fund (with the Small Business Technology Transfer program, known as America's Seed Fund) to help companies get through the earlier stages of product development to commercialization. These are very important programs, especially for university spin-outs – but also for non-academic spin-outs. In fiscal 2018, SBIR and STTR invested over $1bn in health and life sciences companies, a key objective being to translate promising technologies to the private sector.

Changes Apparent In Pattern Of Investments

Medtech areas of greatest interest for investors remain cardiology, diabetes and regenerative medicine – "the usual suspects." Non-traditional life sciences investors are increasingly aware of the broader issues in medtech, and of newer technology developments. Digital health, for instance, has encouraged investors to become more active in medtech. Indeed, the tech part of the equation is both compelling and unstoppable. Digital health ideas often originate from non-life sciences individuals and organizations. "They don't have the clinical background, but they've come up with a cool concept," said Gray. And tech solutions to clinical problems can be a compelling notion, and help bring new investors into the digital health space.

Investors from outside the US – from China and also Korea, for example – have lately been more active in investing earlier in life sciences generally. It has been a feature of many partnering meetings for medtechs, in and outside the US, that Chinese VCs have a large presence, either formally or informally. But the US-China tariffs standoff has changed that a little in recent months. Until mid-June 2018, China's investment progress vis-à-vis

US medtech start-ups was "going fine," but lately many Chinese companies have come under pressure to ensure cash does not go into the US. This has made it difficult for companies funded out of China to move forward in the US market.

Korean investors remain active in the US market, and indeed, several TCG client companies have Korean capital invested. They tend to be "very selective" investors, but have a deep financial commitment. They are careful to ensure that companies are properly funded and have the right resources to expand globally. "But when they do get on the map, they are solidly on the map," said Gray.

He reiterated that there is enhanced investment from accredited private individuals, angel investors and even health-care system corporate VCs and other institutions, who are getting more adventurous with earlier-stage companies. At one time, companies seeking capital were required to have a product cleared or approved for the market or to be generating revenue: an investment candidate company was one that was actually acquiring some market share. But that's changed, and so has the presence of family-owned investment offices.

Economic Issues Dominate Thoughts And Planning

Regulatory is no longer the biggest issue in getting onto the market; now it is reimbursement for many companies. "Some of the recent US medical device regulatory reforms have been encouraging for medtech companies; but reimbursement and insurance coverage, and developing a reliable business model, particularly in ehealth, digital health and mobile health – there are economic issues that are occupying more thinking time and requiring more effort to resolve than historically has been the case," noted King.

King also sees the attention paid to regulatory affairs starting earlier and earlier in the planning, and often at the very beginning of a company's life cycle. Methodsense is a global regulatory affairs and quality assurance consultancy that helps companies with FDA and other regulatory agency processes to obtain market entry for medical device products. Early regulatory attention on the part of manufacturers is, in many respects "a critical consideration or even a determinative consideration on capitalization," said King. And it's as much a factor in the US as globally. "These early-stage concerns speak to the knowledge of the investor population. Investors want to qualify an investment by assessing more thoroughly regulatory risks, including the risk classification of the product, the kinds of testing required for market entry and, the biggest risk, whether a product requires a clinical trial," he added.

EU medical device manufacturing companies are currently experiencing a great deal of change with the forthcoming Medical Device Regulation (MDR) ISO 13485:2016 and the reshaping of other standards, IEC 60601 on EMC testing, for instance. "They fall under the radar screen for much of the industry, but they chew up cash flow very quickly," said King. In short, the pressure EU regulators are putting on medtech companies is only increasing.

In the US, the FDA is driving to simplify matters in an ever-more-complex regulatory world. Its Breakthrough Designation is a welcome change, but Gray cautioned that "no FDA shortcut, in the end, makes it less expensive." FDA shortcuts tend to mean "pay later." But crucially, it's all about getting to market, and breakthrough medical technology and digital solutions solve certain problems.

But in summary, while still difficult, the transactional challenge in getting product clearances or approvals is perceived to be less of an issue. By contrast, reimbursement brings with it a relatively greater sense of challenge. "While the transactional nature of regulatory isn't necessarily any less challenging, the 'pain' is now more on the reimbursement side," said Gray.

Viable Business Models

The acknowledgement by companies of the need to better understand the markets they are entering, and specifically the clinical problems they are solving, while also confirming that people are willing to pay for the technology, is another factor in the maturing of players in the medtech sector. This, along with the trend to earlier-stage investment (see above), is the standout feature in today's evolving medtech ecosystem.

Companies are now aware of the need for an economic – or business – model that shows who will make money with the device, and the nature of the insurance and reimbursement landscape. It's not a new consideration – and neither is regulatory – but it is now being factored in more. "It is absolutely critical that you have a viable business model, and that you are able to effectively argue for that model," stated [add speaker name].

This is where value-based health care models come into play. VBHC must have a global outlook, and not just in geographic terms, but from the lab to the point of sale, to postmarket and to product improvements down the road, said Merz, adding, "Our business model as a consulting firm is to have an impact on the business goals of the

company, and not in a transactional way." Merz is TCG's European lead on medical devices, pharma and biotech.

Workflow Considerations

Clinical/economic considerations are yet another key area. "Understanding the operational aspects of your product or service is important; it helps to further de-risk early investment," said Gray. Solving clinical problems and delivering economic value is a realizable goal, "but how does this product or service fit into the clinical workflow?" Does it make things easier, faster, better? "Emerging companies – and products – can easily be killed by that problem." Understanding a product's fit with clinical workflow, and how it affects overall quality of care, is an increasingly important factor to consider early in the product development process. "Founders and executives who address workflow, along with the usual clinical/economic value, regulatory and reimbursement considerations, enhance the perceived value of their product with both customers and investors. This may account for how the capital is moving backwards in the cycle," Gray suggested.

The Evolving Tech Landscape

The current top talking point is artificial intelligence: "Everyone wants an AI product – all you need is developers in the back room – but lots of them!" quipped King. "But it's got to solve the right problem." In fact, this is a challenge more broadly: many AI-driven projects and companies are carried along by the technical capability of what their algorithm platform can do. It may be deep – or machine learning, but they haven't always started thinking about what the platform can do for users in a busy clinical setting. "Is it solving the right problems in a practical way, operationally?," asked Gray.

The big data and predictive analytics approach is happening in radiology already. The direction that medtech business is taking will lead to both market disruption and business tie-ups. "It's a real opportunity in health care: can we leverage that information for predictive purposes?"

Does TCG get a sense that major medtech companies, the Medtronics and the J&Js, are worried? Data technology companies' perspectives on these problems are different than those of traditional medtechs, the group noted. Medtechs are keenly processing what's going on, recognizing that they are behind the tech companies in terms of the technical capabilities of AI. But it is unlikely that tech companies will be solely driving the dialogue.

"Google and Apple are going to help us understand experiences," said King. While the major medtechs will solve different kinds of problems, the big-tech perspective is to look at pattern recognition from actions, events and outcomes, and to devise patient-centric, or process-centric, solutions in the hospital, or more broadly, in the entire continuum of patient care. But there will be more plug-ins and digital surgery partnerships along the way featuring the big players.

The big medtechs should be thinking about how Google and Apple can offer insights into the potential for product solutions based on patient characteristics. Paying for these services – how, when and at what level – is still an open book, but the guiding notion is that data prove the cause-and-effect relationship.

And procedure-specific reimbursement is just one path to revenues – there are others, in Gray's view. "The idea is that we may avoid a bigger cost problem by intervening now," he said. Using data to improve the overall quality of patient care may even be a bigger opportunity. Data analytics can help providers and hospitals, for example, better understand bottlenecks and barriers to achieving their quality goals in a value-based care setting. "Improved care is great for patients, of course, but it also has economic value to health care systems. It better enables them to achieve their desired reimbursement levels linked to quality goals."

There will be winners and losers in this unfolding scenario, but identifying who these will be is not straightforward or simple. "The issues will be different for every single company and product, and it's hard to generalize, as every company has its own formula and way of fitting into the ecosystem," said King. "What will always kill a company is being undercapitalized for what it needs to do. If that is the case, it's going to fail."

Big Questions For Medtechs

Many digital health companies are focused on technology, not the clinical problem. But being very specific about clinical problems is more important than ever. Gray says the biggest questions of all remain: "What's the problem? What's the problem? And what's the problem?" But just behind that are other vital questions, principally, does the solution make sense to clinicians? Do clinicians think it's a problem too? Is it a problem worth solving? And who will pay for it?

Answering these questions, in TCG's world, is increasingly important for success in medtech.