

Georgie Frost: Welcome to *The So What from BCG*, the podcast that explores the big ideas shaping business, the economy, and society. I'm Georgie Frost. In this episode, the medtech market is growing rapidly, but innovation in software and skills is failing to keep pace. What can the sector do to create the conditions for real breakthroughs over the next decade? Joining me is Vikram Aggarwal, global leader for BCG's medical devices and technology work. Vikram, what's your "so what?"

Vikram Aggarwal: Medtech probably matters more than most people realize. It really is a part of your everyday life. So imagine a world where a device inside your body can monitor your heart's electrical activity and then deliver pulses to correct a heart rhythm. Or where you can have a knee replacement surgery with just two small incisions and then leave the hospital the same day. Or where you can see a doctor without leaving your couch. That's not science fiction. That's the reality of medical technologies today.

Georgie Frost: The global medtech market is set to grow from around \$540 billion today to nearly \$900 billion by 2032, reshaping how we prevent, diagnose, and treat disease. Yet while devices keep advancing, software still lags, with capability and talent in short supply, even as demand soars. So how can the sector build the right environment for innovation and inspire the next generation of biomedical talent?

Vikram Aggarwal: When you go into a hospital room, for example, and you see all the beds, the monitors, the pumps, that's innovation for medtech companies over the last 50 years. When you measure your heart rate through an Apple Watch or a Fitbit, that's medical technologies. When you look at pictures of x-rays that you can see in your patient portals, that's medical technologies. When you put contact lenses in your eyes, that's medical technologies.

Up to 30 million Americans will probably have an implanted medical device in their body at any given time. That's medtech. So it really is quite pervasive. It is really quite broad. It really is the confluence of medicine and technology in a way that you just don't see in any other industry or any other sector. It is really quite a huge contributor to societal benefits over the past 50 years.

Georgie Frost: So where at the moment are you seeing some of the most exciting innovations happening in medtech?

Vikram Aggarwal: If I look out to sort of the next 10, 15 years, where do I see the next wave of innovation coming? There's a number of really, really interesting themes, right? So I can't start without talking about AI that is disrupting industries and businesses everywhere, but is really disrupting health care innovation as well. And medtech actually has been at the forefront of AI, and you may not even realize it.

So 70% of FDA approvals today that are classified as a software, as a medical device comes from radiology and diagnostic imaging. That was probably one of the first areas where there was really established pathways for how you could use software and AI to improve decision making and be able to diagnose things better. But we're seeing that advance even further into chronic disease management, into digital diagnostics. So I think that's going to be an area of continued opportunity to increase patient access, to reduce patient cost, to improve outcomes overall.

The other big trend, and this is probably not recent, but I think is accelerating, is the adoption of robotics. So 25 years ago is when you had the first Da Vinci robot came out. For those of you not familiar with Da Vinci, it was the first general surgery robotic system that allowed you to dramatically reduce the amount of time a surgery took and also reduce complications and also reduce hospital stays.

But now robotics are pretty much in every medtech category you can imagine, whether it's orthopedic surgery, cardiac surgery, you're seeing that in eye surgery. And the scale at which that is happening is phenomenal. And also the fact that it's happening in smaller and smaller footprints so that you can now perform these types of procedures in places that you couldn't before.

Georgie Frost: I'm curious to understand a bit more. You're focusing on innovation here. Which medical areas perhaps get the most attention? Where does investment go? Is it driven by business opportunity or academic or clinical priorities? How has it worked out where innovation goes?



Vikram Aggarwal: For the longest time, there's been so much unmet clinical need and opportunity spaces for medical technologies to have benefit that it naturally attracts investment and naturally attracts companies that are innovating in those areas, because that's how they will be able to also turn that into a profitable venture for their companies. And at the core of that is investments in R&D, right?

So medtech historically invests anywhere up to 10% back into innovation, strategic ideation, clinical development, post-market surveillance. Just making sure that medical devices are continuously hitting the market. What's interesting, I would say over the last little while, is that innovation's gotten harder. So we've seen the number of approvals drop over the last five to ten years, probably about in the order of 40 to 50%.

We've seen the cost go up. So the average approval used to cost maybe \$5 million. And now that's increased 3X to \$15 million. And that's because the problems that you're trying to tackle are just getting harder. Some of the low-hanging fruit, so to speak, you've addressed some of those big, big areas. So then to make the justification to go after other therapeutic areas, it requires additional investment.

The science problems are harder, the engineering problems are harder, and that's just the nature of innovation. In the same way that pharmaceutical industries went from some of the biggest areas like cardiac and general wellness to now more targeted areas within oncology or rare diseases. I think some of that's going to naturally happen as you start to reach the limits of what you can innovate within to address those really, really big buckets of clinical need. But in the end, it's a virtuous cycle that starts with knowing where the clinical opportunities are.

Georgie Frost: You talk there about the barriers to medtech innovation, some of the low-hanging fruit has gone. Some of the questions and the things that you're trying to solve are a lot harder, but what are some of the other main barriers to innovation today?

Vikram Aggarwal: Listen, they're barriers, but they're there for patient protection as well. So obviously health care is a highly regulated industry. And regulation can be very, very important in terms of ensuring patient safety, in terms of ensuring that effective devices are put to the marketplace. It is a confidence in the trust that enables the entire system to work. Because you know that when you're putting things into market that has gone through the rigorous review and detail.

But regulatory burdens can also slow down innovation. And so how do you find that delicate balance between making sure that products are reaching as many people as quickly as possible, but that they're safe and effective for long-term use? I think that's a never-ending tension, but the industry as a whole is committed to that, right?

This is not something where they shy away from the regulatory burdens, but it's just around how do you partner with regulatory agencies to find the fastest way is another facet of the health care system, and that's reimbursement. Just who and how do these different therapies and payments get paid for? Is it the patient, is it the payer? Is it the societal system?

And I think time and time again, it has been shown that medical technologies have the ability to bend the health care cost curve, improve patient outcomes, and justify the cost for these interventions. That is, again, both an important hurdle to hit, but again, can also reduce the amount of innovation you might see if there isn't an easy pathway to be able to create reimbursement. So those are a couple of the challenges we see. I would say then on top of that, there's obviously science and technology barriers as well.

But I think that's where the fun begins, right? That's where I think there's a lot of appetite, a lot of super interesting emerging technologies that are happening on the material science side, in terms of drug device platforms. We talked about AI of course, but there will continue to be that overall progress that you're going to see in medtech that benefits from all sorts of scientific domains.

Georgie Frost: How does software innovation compare with hardware in medtech? What are the factors that influence the pace of that?

Vikram Aggarwal: Medtech has historically been a very hardware-driven industry. It was about



building boxes. It's about building things that are very tangible. The first ever medical device, you may not know this, was a prosthetic toe back in the Egyptian days.

But now we live in a software world. There's no such thing as a hardware device. At the very least, it has integrated software in it. So these are hardware/software combinations. I mentioned the pumps that you see in a hospital room that's delivering, for example, IV solutions. Back in the day that used to be gravity, that just used to be how you administered it, and it was just a system.

But now these are electronic systems that have feedback loops that monitor the pace at which the drug is being delivered, that can signal when there's events that are happening, that can trigger clinical intervention. So that's the way that software is actually enhancing and augmenting these hardware. And now you're getting to a point where it's no longer software in a medical device, but it's software as a medical device.

Georgie Frost: What do you mean by that? Give me some examples.

Vikram Aggarwal: Yeah, so one would be, for example, diagnostic imaging. The MRI machine is the one that's collecting the image, and then you typically had a radiologist that would read the image, and they would say someone has a broken limb, or there's a tissue damage, or whatever it might be.

But now you have software algorithms, imaging recognition that can actually look at images in seconds and be able to identify areas where, yeah, maybe you still need a second set of eyes from a doctor, but it's no longer now the manual process of holding it up to a light and seeing what the x-ray is. But it's image recognition that happens.

We're seeing clinical decision support systems where you can now integrate health information from all sorts of different devices. So if you just take, for example, if you ever have a family member that has cataract surgery, there's multiple steps that have to go in to measure the size of the eye, to measure the size of the cataract, to know where to make the incision.

And the skill of the surgeon used to determine a lot of that. But now what you're seeing is that

information can actually be fed to the surgeon that suggests a right clinical path or a treatment path. So it augments and enhances clinical decisions so that it reduces error rates and improves outcomes. It actually reduces the time also required to do the surgery, and therefore you can see even more and more patients with that same physician. So those are just some examples of where you have software that can really, really be quite powerful in terms of enabling better outcomes.

Georgie Frost: So I know even though you said hardware comes with software anyway, so they come as a team, but is it fair to say that there is still a gap between innovation with software and innovation with, and I quote, "just hardware," but I appreciate that it is a more complex situation than that, but is there a little bit of a lag, as it were, and how do we close it, if so?

Vikram Aggarwal: Listen, the clients that I work with have been investing in capabilities and talent. So what used to be the domain of electrical engineers and mechanical engineers, they're hiring software developers. They're hiring data scientists. They're hiring data engineers. That is just the currency of which business works and which innovation works. So there is that shift. That shift sometimes takes time.

And then again, there's just expertise that has been built over decades. So if you're developing the world's best widget, it's hard to then go and suddenly change that paradigm into something else that you're not. It's hard for a hardware company to become a software company overnight. And I think that's a little bit of the lag that you're seeing. And then on top of that, you throw in the stuff that I mentioned earlier, which are there regulatory pathways that can handle software solutions? Up until recently, there wasn't.

So the FDA actually has made tremendous strides in terms of establishing regulatory pathways around now you can actually understand how to evaluate whether a software is safe and effective. It was easier to do with a hardware solution. Reimbursement pathways are now catching up where CMMS and others are creating codes for interventions or diagnostics or therapies that are completely software driven.



So you need the whole ecosystem to work together. It's not the responsibility of just the medtech companies, but we definitely see that shift and change happening. But that's why you probably see a bit more of a lag vis-a-vis other industries.

Georgie Frost: So paint for me if you would, Vikram, your ideal innovation environment for medtech. How do academia, the industry, clinicians, regulators, how do they all work together?

Vikram Aggarwal: Just like you describe, in unison. But no, I'm a firm believer that innovation does not happen in silos. That you need this collaborative ecosystem that feeds off of each other. So I did my PhD research in biomedical engineering. It was around neuro-prosthetic devices.

If you want to talk about science fiction, talk about this. That this is using signals from the brain to control different devices. In my research, it was to control prosthetic devices. Prosthetic devices historically were mechanical systems. It was pulleys to be able to do different things, but now you're actually tapping into the central nervous system.

You're actually able to understand what are people thinking, what's their intended movement, and now you're sending that signal to a futuristic robotic arm that can do all the different manipulations that a human hand can. How and where does that research start? That started with the government. That started with investments through DARPA, which is a Defense Advanced Research Project Agency.

You may know them for investing in the internet before there was an internet. But that technology spurred again, academic partnerships, where then you had basic science research into neuroscience to understand how to decode motor movements. It spawned in new industries around materials. So how can you create robotic interfaces that can be integrated directly into your body? It resulted in advances in batteries.

So how can you actually make prosthetic devices that can last an entire day? Now you're seeing the fruition of that, where you're starting to see this technology commercialized. I think we all

probably have heard of Neuralink and Elon. That work started 15, 20 years ago, and it started through intentional investments in ways that have now created incredible commercial markets for companies to take it to the next step. So to go from bench to bedside as we like to put it. And that takes the whole system working together. That for me is the dream. And I think that has been the successful ingredients for innovation for the longest time. And I think that's hopefully going to continue.

Georgie Frost: It seems crazy just listening to what you're saying, because the word cool comes up quite a lot in my head when you're talking about all of this stuff. And yet we certainly in the UK and in Europe, there is a STEM skill shortage, and I imagine the situation is the same in North America. How do we make medtech appealing for the next generation when it couldn't sound cooler.

Vikram Aggarwal: Through podcasts like this?

Georgie Frost: Absolutely, right. Good answer.

Vikram Aggarwal: There you go. I've already told my son that he shouldn't be a doctor. He should be a biomedical engineer. So I think we can all do our parts here. No, but it's a great question, Georgie. I think investment in STEM is critical, important. And again, the lines are blurring between traditional disciplines around medicine and engineering, and whether it's electrical engineering, computer engineering, which is what I was historically, that all of these are now becoming interdisciplinary domains. And I think that is what's exciting.

The other thing to note here is that a large part of innovation on the medtech side came from the US. And now you're actually seeing a lot of innovation coming from other parts of the world as well, where there has been significant investments in STEM. This is no longer about medtech companies serving emerging markets because those are patient populations that they can help.

But now you're actually seeing innovation coming out of those markets that can actually now be served globally. And that's because you're seeing, again, tremendous investments in software development, in hardware engineering, in manufacturing capabilities that allow you to get to



things to scale. So you're seeing that happen now at a global scale, which I think is again, another recent phenomenon.

Georgie Frost: You mentioned earlier in the podcast about what you saw likely to be on the horizon over the next five to ten years. I wonder what you think will bring the most value? Are we talking the AI-enabled diagnostics, robotics, something under the radar even? What do you think will bring the most value?

Vikram Aggarwal: So it's hard to say what is that one thing that is going to suddenly create a brand new market? Is there an Ozempic on the horizon? I don't think it's quite like that. I wouldn't say it's a steady drip either. I do think there's just tranches where you suddenly see technology has this amplifying impact and that just spurs more.

I truly do believe that we are in an AI generation, that we are only scratching the surface right now in terms of how that can improve all facets of business, and particularly on the innovation side in terms of the products that can be developed. Again, can I put a number to that value? No, but do I think that's going to have the outsize impact? Absolutely. We're also seeing, I would say, a blurring of consumerization in health care. Which I think is another theme that opens up just the possibilities of what medtech could become, right?

So what do I mean by that? We have consumer companies that are now entering into health care. So think of the Fitbits of the world or the Apples of the world that are trying to use their core technology, which is highly consumerized, to be able to gather health information that can then be shared with the users that can again, create wellness.

You have health care companies or medtech companies that are trying to become consumer companies. So how do I get even closer to that consumer? How do I start to deploy tactics and tools that you might associate with a retailer, but now is actually a medical device company? So thinking about loyalty programs and promotions that actually encourage use, or like I said, contact lenses as a medical device. If that's something that you can go into a store and buy contact lenses. So how do you become a retailer in that regard?

So that's where I think there's another convergence of happening, and what that's resulting in is devices that are now 24/7. So it's continuous monitoring, it's wearables, it's stuff that can be used in at-home environments. We're seeing a ton of proliferation now in terms of innovation in that domain.

And that is just not the historical place where a lot of traditional medtech companies have grown. But we're seeing a lot of startup activity. And we're seeing a lot of folks crossing that line that I was saying that's blurring between more accessible technologies on the consumer side with health care applications.

Georgie Frost: That's an interesting point. Is some of most exciting stuff happening at startups or more established companies?

Vikram Aggarwal: And this I would say maybe is one of the bigger opportunities if the ecosystem that we know it can help address and solve. It is hard to be a startup in the medical device space. It is hard. It is hard to raise funding. It is hard to get products to market in a timeframe that matters to investors because again, there's many, many barriers and steps along the way.

I said the lower hanging stuff has been addressed, so the engineering and science problems become tougher. So that I think is actually one area where if there's ways to foster even more innovation outside the four walls of traditional companies that can have massive benefit. And we're starting to see that. We're seeing companies now investing back into academic research through seed grants and other mechanisms.

We're seeing direct investments into some of these startup companies to help bridge the gap between some of those larger expensive clinical trials to prove safety and efficacy. We're seeing cofunding models. We're seeing just a lot of different innovative ways to help finance innovation that is not just within the four walls of companies that will have huge benefits.

Georgie Frost: Vikram, we've spoken about the "so what," what about the "now what?"...the next step that leaders can take to accelerate innovation or to gain competitive advantage in this space?



Vikram Aggarwal: Yeah. And I think it's many of the themes I've already touched upon. So what I would say is that we can't take medtech innovation for granted. It requires a sustained commitment. It requires a sustained level of investment across all the parts of the health care system. It requires investments in basic science and engineering. It requires reframing the societal compact that we have in terms of the benefits that medical devices can bring.

It requires looking outside just traditional companies and seeking sources of innovation. It requires burgeoning that startup community. It requires looking at markets outside the US as sources of innovation. That for me is a now what, is making sure that we don't take the foot off the gas here in terms of medtech innovation, but finding new creative ways to steer that for the next 50 years.

Georgie Frost: Vikram, thank you so much. And to you, for listening. If you want to read the latest articles from Vikram and BCG's medtech practice, follow the link in the show notes.