



# EY/AdvaMed medtech CEO roundtables

How medtech is addressing  
the challenges and  
opportunities of COVID-19

4 August 2020



Building a better  
working world

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On 4 August 2020, AdvaMed and Ernst & Young LLP (EY US) hosted the first in a series of MedTech CEO roundtables bringing together senior leaders, many of whom are part of AdvaMed's Accel program for smaller medtech companies. The companies at this first roundtable included public companies and companies backed by both venture capital and private equity, covering multiple therapeutic categories and at various stages of commercial development, including companies at the revenue and pre-revenue stages. A second roundtable, to take place 26 August, will assemble representatives of some of the biggest players in the medtech industry, with EY US and AdvaMed aiming to capture the responses to COVID-19 across the scope of the industry.

## Questions and topics

Moderated by Jim Welch, EY Global Medical Technology Leader, and Andrew C. Fish, Chief Strategy Officer at AdvaMed, the group's discussion focused on the medtech industry's response to the COVID-19 pandemic. Key questions included:

- ▶ How have companies pivoted to address the challenges of the pandemic?
- ▶ What lessons have been learned from the perspective of company leadership and culture?
- ▶ In what ways have the needs of medtech's customers changed during the crisis, and how can the industry help?
- ▶ How can companies balance the demands and opportunities of COVID-19 with normal business operations?
- ▶ With the crisis ongoing, how can the industry address the financing challenges it raises?
- ▶ Finally, what will be the enduring impact of the events of 2020, and how will the COVID-19 challenge reshape the medtech industry in the now, next and beyond?

In all of these areas, there was a fascinating array of responses from the group, which we have explored in more detail below.

The discussion also opened other topics for future exploration, including the challenges of international expansion in the current geopolitical climate. EY US and AdvaMed intend to convene future roundtables, which represent an ongoing opportunity to enrich and deepen conversations and collaborations across the medtech ecosystem.

## Medtech's COVID-19 pivot

All of the companies in the discussion have found themselves needing to pivot away from established plans for this year and improvise a response to the disruption that has rocked the industry and the wider global economy. In general, these companies have so far weathered the storm with relative success. One participant described their company as "more optimistic than was the case in late March, when it was planning for doomsday."

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As another participant observed, "none of us were trained to run companies from our dining room tables, but now we've been doing it for 21 weeks." This participant's company has spent the year to date focused on COVID-19 diagnostics while simultaneously addressing the challenges of managing an

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organization based across multiple global locations and with almost its entire workforce now working remotely. The overriding focus on COVID-19 has meant that leadership now involves monitoring the world news closely to track real-time developments with the pandemic.

In some cases, these companies have executed very successful adaptations. One participant described how his company's first-in-human clinical study into remote monitoring was halted in March due to COVID-19. However, the company managed to adapt: it requested a broader indication for its product, covering lower-risk patients, and worked with the FDA, eventually succeeding in filing a 510(k) application within three months. If that application is approved as expected, the company will effectively be commercializing one year in advance of its expectations; "we rolled with the situation optimistically, and were fortunate that the timing was good for our remote monitoring diagnostic."

Success stories like this have been enabled by ingenuity on the part of companies and also by the flexibility of regulators, something called out by multiple participants. One participant praised the "extraordinary response" from the FDA and was "incredibly impressed" at how fast the regulator reviewed their company's *de novo* application and sent back its questions, "moving at warp speed."

## Leadership challenges in a time of uncertainty

In general, the participants agreed that they have had to focus on two overriding leadership priorities: firstly, employee health and management, and secondly, the financial security of the organization. Companies are trying to make progress rather than just survive, but this requires time and secure financing (a potential challenge in the current operating environment, as discussed further below).

The leadership challenge around employees has focused first and foremost on how to keep employees safe. The broader subsequent issue here have been how to continue recruiting and hiring and how to ensure employees are performing when company operations are inevitably disjointed across different locations.

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Dealing with financial security has been a major challenge for smaller medtech companies: it's difficult to innovate when R&D can only be carried out remotely and it isn't possible to convene the stakeholder discussions critical to the medical device innovation cycle. Uncertainty is also a major issue for financial security. The industry faces the pressure of dealing simultaneously with constraints on the demand side and also the reopening of hospitals, driving rising demand. Rather than seeing a single industry-wide pivot in 2020, one participant described a more stop-and-start situation, where the market is sometimes standing still and sometimes speeding up out of control. Companies can control costs upstream and downstream and control customer interactions, but predicting what's going to happen in a month or three months and knowing how to keep people engaged in pursuing opportunities in the face of this overarching uncertainty are tough challenges.

Therefore, one leadership challenge participants have had to struggle with is around demand planning. One participant described the work their company has done to stay on top of forecasting the supply chain and controlling inventory with analytics teams looking at hospital capacity against COVID-19 outbreaks to predict which pockets of the country will be hardest hit. Should companies be beefing up their inventory positions or decreasing their holdings? This is not a normal cycle, and it's difficult for companies to predict and manage the volatility of demand and get a handle on the "pandemic curve."

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## The value of culture in a crisis

One participant suggested that this ongoing uncertainty has required companies not only to be agile and nimble but also to keep the focus tight on long-term growth drivers. Narrowing the focus has been the key to success and to identifying where a company's core value lies. The participant urged that while companies plan for all eventualities, they should also be focusing on just a few core specifics and making sure that this focus permeates through the organization, giving people a clear sense of "why are we here."

This question of purpose speaks to the broader issue of company culture. Participants acknowledged that it's a difficult time to be the sort of leader who controls all aspects of a company's strategy, culture and thinking, because these leaders have inevitably lost control of the total situation with the ongoing disruption. Where a strong culture exists throughout the organization, however, it can act as a powerful force for cohesion during the crisis. As one participant noted: "the biggest lesson is that culture is everything ... you don't know how important it is until you have a pandemic: then you see the importance of a brand you can touch and feel. Culture kept us together."

At present, this participant hosts live-from-HQ sessions every week to keep employees abreast of the latest thinking. The senior team members "make five calls randomly within the organization every day to make sure people feel connected and know what the priorities are." Another participant agreed with this emphasis on internal transparency, noting that while leaders may not necessarily share all the details around company runway or burn rates with all employees, they nevertheless need to ensure everyone knows that this is a pivotal moment.

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## How medtech's customer base is coping with disruption

While companies struggle to maintain and grow their own operations, they also recognize that their customer base is "reeling" from the crisis. The industry can't be blind to the fact its customers are struggling: clinicians, for example, are itching to get back to productivity and trying desperately to build revenues, while simultaneously waiting for the next wave and anticipating being shut down again. Companies therefore need to be considering different aspects of their customers' situation, from hospital economics and how these are impacting hospitals' ability to make investments, to access and trust.

One participant described their company's efforts around access: how can the company become the COVID-19 solution? One value proposition it has identified is its potential to save clinicians from going into operating rooms and reduce personal protective equipment utilization. The company has developed semiautonomous robots as virtual educators, launching these into five hospital systems. In general, participants agree that the demand is there from hospitals for better patient data and tools for remote management of patients, with companies in the discussion also believing that they have tech platforms that can meet hospitals' requirements.

These efforts to address the issues from the customer's side have led to increased interactions with hospitals' leadership teams. One participant described how their company has been connecting with hospital C-suites daily, indicating the high level of trust there is at present. In EY discussions, hospital administrators have mentioned that they expect to rely increasingly on vendors to help them innovate going forward, a great example of how doors that have historically been closed



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are now beginning to open. As one participant notes, this is an industry built on partnership, and at a time when companies could become very introspective, the industry should instead maintain sight of the wider picture. Hospitals are hurting, physicians and the wider economy are under pressure, and the industry should focus on asking “how can we help?”

One participant noted that their company has received a tremendous amount of gratitude because its team has remained on-site amid the pandemic and has aided anti-COVID-19 efforts, such as the logistical assistance it lent to a big Silicon Valley donor lacking a distribution system for the face shields it was aiming to donate. Though it doesn't have the resources to give away, the company offered this assistance nonetheless. Companies can use their strong cultures and personal relationships to assist their partners across the ecosystem.

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## The need to balance COVID-19 efforts with core business focus

As companies look ahead from the embattled present situation, their forthcoming challenge will be how to balance their core business operations with the COVID-19 focus. Participants suggest that the impact of COVID-19 will last for the next three to five years, considering the vaccine timelines and the need for expanded testing programs for populations outside the US. During this extended period, companies need to maintain their business balance while communicating effectively with Wall Street to maintain credibility in the short and longer term.

Of course, the effect of COVID-19 will continue to be felt in all industry subsectors; one participant noted that there is limited “pattern recognition for launching” in the current era, with few historical precedents of comparable systematic downturn from which to learn leading practices. If all stakeholders are trying to

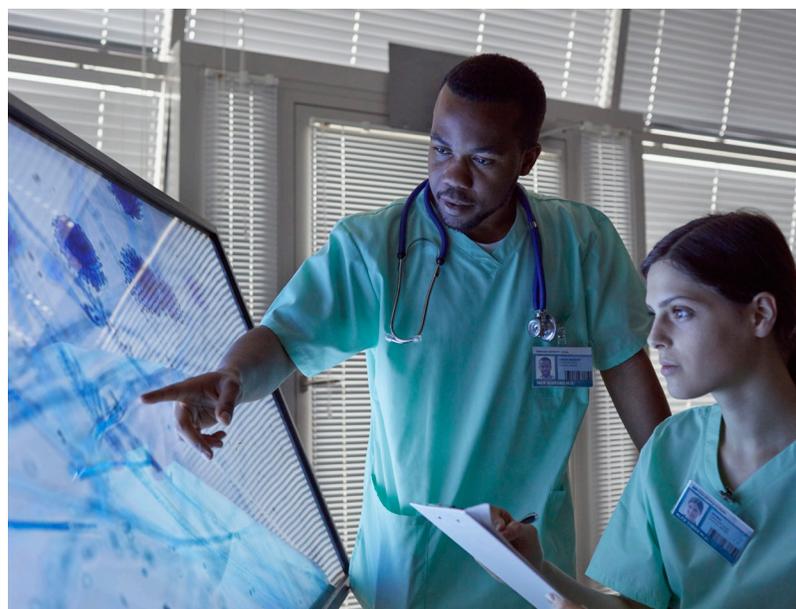
tighten their belts in the wake of COVID-19's economic effects, what impact will this have on “regular” product launches?

Participants also noted that although COVID-19 has opened opportunities, if companies pivot too far and make their entire business model dependent on COVID-19, they face, as one participant noted, “a better chance than not you're going to flame out.” This participant noted that their company therefore needs to “keep driving with one foot on each pedal, the gas and the brake.”

## The financing environment in 2020

Financing also represents an important issue in terms of the long-term sustainability of these companies' business models, with several of the companies in this discussion at a pre-revenue stage. One participant noted that their company's next round of Series B fundraising was predicated on milestones from a halted clinical study. The crisis placed pressure on the company's limited cash resources. Smaller medtechs in general have had to do “what entrepreneurs do best: plan for uncertainty” – including trying to calculate what level of cash reserves they may need to survive.

Questions of longer-term sustainability are partly dependent on the industry's levels of investment. The medtech innovation ecosystem depends heavily on venture capital, and the



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industry needs to monitor the risk of investors losing value on medtech investments. Similarly, medtech has historically been built on acquisitions, and this side of operations has been put on pause. Discussions with bankers illustrate that M&A has been constrained by limitations on companies' ability to do due diligence, to have customer feedback sessions and to carry out other interactions necessary to the acquisitions process. Carrying out valuations is a significant challenge at present: should companies work off 2019 figures and skip 2020 altogether?

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John Babitt, EY Medtech Strategy and Transactions Leader, noted that when the initial outbreak occurred, there was a pivot toward dropping M&A deals that were not far advanced, with large medtechs frankly assessing which companies would struggle to survive the crisis. Nevertheless, capital markets have continued to be available, and large medtechs have so far been able to recapitalize (debt offerings and follow-on offerings being their major focus). While we've seen little in the way of megadeals within the industry recently, there has been significant activity in bolt-on acquisitions. If the industry rebuilds a sense of normalcy into the fall, the high level of available capital could trigger an M&A acceleration.

Participants recognize that their companies need to keep making progress in spite of the current disruption. As one participant noted, potential customers, acquirers or investors "are all going to say what have you done? Saying we couldn't get into hospitals, or we couldn't get things done because the FDA was overwhelmed, etc., won't be an excuse."

## Next and beyond: the lasting impact of COVID-19

One area where the current crisis has, if anything, boosted confidence in the industry for the longer term is in showcasing the need for cutting-edge technologies that the health care system is presently lacking. Investors, one participant argued, will stay with medtech because it has become a "must-have industry." Another participant agreed: "we've got technology that can change the world; we're going to come out the other side – people need our tech more than ever." This includes technologies like AI and remote management, the urgency for which is now becoming more evident. The pace of technological adoption has picked up in 2020, one participant argued, but "these are things that were going to happen anyway; it was always going to happen in five years but instead it happened in five months."

Other participants agreed that this is an important pivot point and will help determine the role that digital technology for remote management and other functions will play in the future and how it gets embraced and used by hospitals and other customers.

As one participant argued, "tragic as all of this is, it's given us unique positive opportunities to pivot business to more efficient (and cost-efficient) approaches that wouldn't have happened for years to come." Medtech has cause for optimism in the fact that the current situation has "forced us to be really creative about how to innovate pieces of the puzzle" and "do more with less." This participant described how their company is developing a hybrid model allowing it to work either remotely (for example, in terms of training physicians) or in-person, building greater resilience and efficiency.

Another participant suggested the scale of the present opportunity by saying "this is a moment when some future superstars will emerge, and if we didn't have this shock to the economy and to the industry, maybe this would never have happened." Participants agreed that seizing the opportunities of this pivotal moment will definitely involve strengthening relationships with their ecosystem partners: "we need to be there for our customers." While there has always been rhetoric about partnership in the medtech sector, "this is an opportunity to solidify that partnership we all talk about, this is the chance to make it real. We'll be talking about 2020 for years: *'what was your experience? how did they do by you?'*... If we do right, they'll never leave us."

# Contacts



## Jim Welch

EY Global Medical Technology Leader,  
Ernst & Young LLP

[james.welch@ey.com](mailto:james.welch@ey.com)

<https://www.linkedin.com/in/jim-welch-111a2014/>



## John Babitt

Medical Technology Strategy and  
Transactions Leader, Ernst & Young LLP

[john.babitt@ey.com](mailto:john.babitt@ey.com)

<https://www.linkedin.com/in/john-babitt/>

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