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'Blah-Blah' May Subside, But Harnessing AI Ethically, Impactfully Is Key For Medtech In 2024

2024 Crystal-Gazing With Industry Leaders

by Medtech Insight Team

Views from medtech industry leaders and investors on the most significant uncertainties and opportunities facing the sector in 2024.

Medtech Insight reached out to leaders in the industry to ask about the most significant uncertainties facing their role, organization or the industry in 2024. Here's what they had to say...

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Ken Stein
SVP and Global Chief Medical Officer
Boston Scientific

Doctors today are drowning in data. When I was in med school, the amount of medical literature doubled every six years; now it's every six months! And while the pace of medical science is a good thing, there's no way a practitioner can keep up. This is where their challenge becomes our challenge: how do we enable physicians to make sense of the rapid innovations that are happening, so that they can actually apply it to enhancing patient care? That's where digital and AI tools will play an important role.

One way is through the use of implantable devices that are programmed to track health data, then turn that data into actionable information. That's something we're doing with HeartLogic, an implant which identifies signals that could indicate worsening heart failure, then alerts the practitioner. A second way is to apply digital and AI tools to processes that typically require a lot of specialized skill and training, making it more feasible for the typical interventionalist, as we're doing with AVVIGO+ in the realm of echocardiogram. A third way is by harnessing vast quantities of real-world data from electronic medical records to better inform clinical decision-making, like we did in the REAL-PE trial, which studied the use of EKOS for pulmonary embolism treatment.

This rapid pace of change can feel like an overwhelming challenge to physicians, but it's work like this that transforms the challenge into an opportunity to improve patient outcomes.

Read about the American Medical Association's new principles for augmented intelligence development, deployment, and use.

Wyatt Oren
Director of Sales for Telehealth
Agora

As we head into 2024, one of the most significant uncertainties facing healthcare is how to ethically yet impactfully harness AI, chiefly around patient data privacy and algorithmic biases. At its core lies the issue of data – an invaluable asset for advanced AI systems, but one that presents risks around consent, security, and improper usage. Predictive modeling using these datasets poses a risk as well; biases within these algorithms could ultimately enable unequal treatment across patient demographics.

These concerns guarantee that as AI usage grows in healthcare, regulatory scrutiny will intensify. While positive in the long run, in the near-term this is likely to spur uncertainty as organizations struggle to comply with more stringent policies around AI system development, testing, validation and responsible data usage. However, establishing appropriate technical controls and guidelines is crucial to ensuring AI can be leveraged safely to enhance the healthcare experience moving forward.

Ultimately, AI presents immense opportunities in healthcare. By proactively addressing uncertainties head-on, we can pave the way for AI to propel enhanced access, equity and outcomes for all patients while retaining public trust.

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Read more about responsible AI use in this interview with Medtronic Endoscopy's chief artificial intelligence officer.

Michael King
Senior Director, Product & Strategy (Medtech)
IQVIA

Grasping how to better apply AI technologies to support an augmented QARA professional.

Against a backdrop of continuous regulatory change, financial pressures and product complexity, the healthcare industry will advance in understanding of how to effectively apply AI technologies to the Quality, Regulatory and Safety arenas and recognize where the AI solutions themselves are limited in application through operational constraints such as data quality, data privacy, solution cost and regulatory controls.

Read about the EU AI Act's implications for medical device companies and *quality management systems.*

Deepak Sahu
Managing Director
Trinity Life Sciences

Persistent macroeconomic pressures are bearing down on medical device firms, while China's anti-corruption measures pose a potential threat to medtech revenue streams. Investors are scrutinizing medtech companies for insights into the long-term effects of weight loss drugs on their bottom lines. The industry's sustainability pivots on diversification and strategic identification of growth areas.

Post Acute Care (PAC), encompassing Skilled Nursing Facilities (SNFs), Home Health Agencies, Senior living facilities, and Hospice, emerges as a growth opportunity for 2024 if executed effectively. In 2022, post-acute care experienced a record number of mergers and acquisitions, with SNFs reaching an all-time high of 216 deals and senior living facilities totaling 527 deals. While medtech companies are adapting their business models, pricing, and products to align with PAC resource constraints, much work remains to unlock the segment's full potential.

Venturing into PACs with sustainable business models presents both a challenge and a five-year opportunity in the current environment, demanding strategic navigation for 2024 and beyond.

Read more about the shift in heath care delivered in ambulatory settings and at home.

Brittany Barreto
Founder and CEO
FemHealth Insights

Biggest uncertainty for 2024: Will large companies in health and wellness approve budgets to do significant work in women's health? Or will they continue to stay on the sidelines? There are conversations around investing in women's health market research, acquisition, and product development. Unfortunately, there are still minimal conversions of these conversations into paid contracts. Femhealth Insights believes the women's health innovation industry is still nascent and we do anticipate deep financial commitment to eventually happen. Will it be in 2024?

Read more about Barreto's work to drive awareness, education and investment in women's health.

Mannesh Jain
CEO
Mirvie

The biotech industry has been hit especially hard with the 2022 surge in interest rates and the XBI down ~60% from its high in 2021. This is partly because the longer timelines to get products to market are now being discounted at a much higher rate by investors.

I expect significant uncertainty to continue into 2024. Make no mistake, the pace of innovation has not slowed; many would even say that it has accelerated. However, funding will continue to be challenging in 2024 as biotech startups navigate from creating innovation to getting actual products on the market.

There are some encouraging signs as some molecular testing/diagnostics companies have recently increased their revenue guidance. This shows that despite the economic downturn, people will continue to spend on testing and treating for life-changing, "non-discretionary" conditions like cancer or prenatal health.

Read about accelerating innovation in women's health, including Mirvie's FDA Breakthrough Device-designated blood test to assess risk of developing preeclampsia.

Naomi Schwartz
VP of Services
Medcrypt

I think some smaller organizations are struggling to implement cybersecurity in a tightening funding environment. Large companies are struggling against inertia; the thinking runs along these lines: 'We didn't share much cybersecurity documentation with the FDA in the past, we got cleared or approved, so why should we change now?' The uncertainty is – will the FDA crack down and start issuing significant deficiency letters on cybersecurity, and if so, when? Questions people are asking are: will it be across the board, for all devices that qualify for the definition of 'cyber device,' will it include devices that don't meet the statutory definition, and how hard will the FDA push back? The short answer is, yes, FDA will ask for cybersecurity documentation, commensurate with the risk of the device, for any device containing software. For 'cyber devices' the full statutory requirements are expected. For higher-risk devices (often coming with higher benefits to patients), the expectations will be most stringent. When will this happen? It's happening right now!"

Read about genetic testing company 23andMe's recent data breach affecting 6.9 million customers.

Frans Cromme
CEO
ViCentra

As we just launched our AID [Automated Insulin Delivery] proposition in three countries, and initial interest is high, it will be scaling up. Our new production facilities are well-equipped to cater to this growth, but we also want to maintain our exceptional customer satisfaction whilst scaling up quickly in multiple countries. The key strategy to solve these challenges is digitalization, such as online training videos to support the onboarding journey.

Read about ViCentra's launch of a hybrid closed-loop diabetes management system in partnership with Diabeloop.

Jan Van den Berghe
Co-founder
Novalis Fund

Next year the main issue in our VC world is valuations. There has been turbulence in the recent past and at the moment there is still uncertainty. We'd like some stability. It almost doesn't matter at what level, but just something we can rely on for a few years to come. As VCs, we're dealing with plenty of uncertainty. We don't need the interest rates one on top of it all. Similarly, of course, we don't need inflation either. So hopefully this will land somewhere

where rates are what they are and go down slowly at some point in 18-24 months, and all else follows from that. Fingers crossed.

Staffing is a problem too, though. Particularly also the willingness and ability of people to move between countries or continents. Now is not a time for young families to hop around, which is not good for any business, but less so for startups who need these kinds of adventure seekers.

I don't think the wars in Ukraine and Gaza will matter much, by the way. Largely sideshows, away from the main stage. Main stage is probably the coming rise of India (over a frustrated China). AI will get used, but the blah-blah around it will subside. It'll become integrated in everything, much like the internet and mainly for back office stuff.

Read more from Van den Berghe on how FDA Breakthrough Device designation may factor in valuations.

Hugo Harrod
Partner

MVM Partners

The biggest uncertainty in the sector is the extent to which NASDAQ opens for medtech IPOs in 2024. If NASDAQ remains closed – and it may, given the many macro uncertainties including the US presidential election – valuations for private financings and M&A will also suffer.

Read more about the dramatic slowdown in IPOs and M&A in medtech in recent years.

Simon Turner
Partner
Sofinnova Partners

As an early-stage investor in healthcare, we are, like many others, affected by the macro-economic environment, including rising interest rates and the subsequent squeeze on costs from the private and public sectors. Healthcare is a constant need and fundamental right, so our sector may be somewhat more insulated from these macro changes.

Our portfolio companies are also feeling the uncertainty, though it isn’t all bad: Budgets are being tightened, but because a lot of our companies focus on augmenting healthcare practitioners’ capabilities and improve cost-care-effectiveness, they are sought after.

Another uncertainty is procurement, which remains an evolving process as many healthcare systems have yet to put in place standard operating procedures (SOPs) for procuring Digital Medicine services, partly because they tend to rely heavily on AI. The net effect remains to be seen, but given our focus on services that demonstrate significant healthcare impact, and the general demand as healthcare systems remain constrained both by costs and healthcare supply, we remain optimistic that the space will continue to grow at a fast pace.

Despite these uncertainties and complexities of the current market, we remain confident that our focus on health sciences is a key strength when added to our deep-rooted network and dedicated investment teams that will enable us to help our companies navigate the challenges and opportunities that lie ahead in 2024.

Read about Sofinnova Partners’ $200m digital medicine fund.

Tasneem Dohadwala
Founding Partner
Excelestar Ventures

As for the obstacles the industry may face in the upcoming year, and advice for tech entrepreneurs, it's crucial to articulate your vision and set a strategy to enact that vision. Understanding your cash needs, aligning milestones with market values, leaving ample time for fundraising, comprehending the intricacies of your supply chain to prevent delays, and being aware of customer sales cycle and clinical trial work are essential. Additionally, entrepreneurs should be prepared for customers tightening their belts.

In this challenging fundraising environment, companies might encounter difficulties due to nervous LPs, funds struggling to raise cash and conserving it for follow-on investments. Uncertainty and fear of perceptions, large companies refraining from trialing or scaling contracts, and startups missing targets due to sluggish enrollment impacted by the pandemic and missed milestones further contribute to the fundraising challenges. The absence of exits adds to the complexity, as companies are compelled to persist with the IPO window shut and M&A activities sluggish, and funds face constraints in fundraising, given the lack of robust exit performance and tied-up investor cash.

Considering the impact of inflation on venture capital, it creates a sense of cash scarcity, making everything more expensive, and talent costs rise significantly. Furthermore, inflation exerts increasing pressure on the supply chain, posing additional challenges for venture capital endeavors.

How will Excelestar Ventures approach this climate? Stay the course, looking for solid companies that have selected strong markets that they can disrupt with truly innovative solutions. We also look for class A teams that understand their cash needs. We also believe tough times breed innovation and disruption – strong companies emerge out of recessions. We never lose sight of the fundamentals that are at the core of our investment thesis and diligence process.

Read more about medtech investment strategy in a difficult environment.