



The Future of Medtech:

The Role of AI





Overview

Balancing innovation and risk mitigation: The role of AI in medtech

The medtech industry is at an important and exciting juncture. The adoption of AI promises to drive rapid innovation, particularly in catalysing tangible and significant improvements in the safety, effectiveness, accuracy and quality control of products.

At the same time, AI adoption presents challenges in terms of ensuring rapid innovation is balanced with risk mitigation. For companies that can achieve that balance - and for the patients they serve - there are vast health and financial benefits on the horizon.

The medical device sector is well established in both Europe and the United States. Today, Europe comprises 26.4% of the global market, making it the second-largest regional market after the US, which accounts for 46.6%. However, the dynamics of each regional market are quite different:

- In Europe, the industry employs over 850,00 people across over 35,000 companies, of which almost all (92%) are small or medium-sized. The market was estimated to be worth around €160 billion (\$174 billion) in 2022, with CAGR peaking in that year at 11.4% ([citation](#)).
- In the US, medtech directly accounts for nearly 519,000 jobs across a much smaller base of around 6,500 companies. The market was worth \$573 billion in 2022, with CAGR falling to 3.5% in that year after reaching a high of 16% in 2021 ([citation](#)).

These figures show that industry growth and capital investment have dipped since the exceptional peaks of the Covid-19 pandemic ([citation](#)). With the unprecedented urgency of that era thankfully behind us, a new catalyst is needed to re-ignite growth. AI can be that spark.

But to realise the full promise of AI-based value creation, medtech companies must navigate stringent **regulatory, data quality and privacy concerns**, as well as address significant challenges in attracting **top talent**. As this report will show, these challenges could be mitigated in three ways:

1. Turning to external partners with specialised expertise at scale
2. Increasing investment in building a strong data foundation
3. Implementing a responsible AI framework, aligned to evolving regulations, to enable safe use of AI

To assess what lies ahead, including the opportunities and challenges presented by AI, Cognizant and Microsoft commissioned a quantitative survey of 200 medtech decision-makers across the US and Europe. This report outlines the findings from that survey, with additional insights from third-party research, and serves as a guide to navigating the future of medtech. It will cover:

1. The promise of AI in medtech: Which areas of the value chain are likely to benefit most?
2. Key challenges in realising the potential of AI and concerns raised by the industry
3. How medtech companies can overcome the challenges and address the concerns



The Promise of AI in Medtech

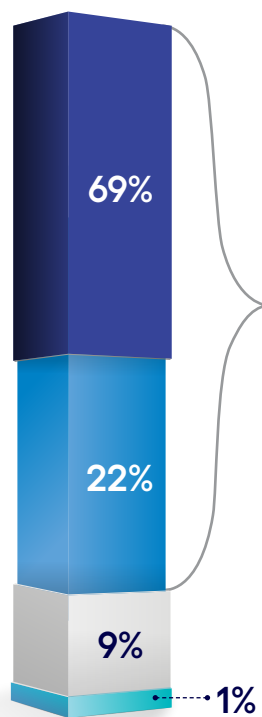
Medtech decision-makers are, almost without exception, excited about the potential improvements AI can have on medtech products. They see the opportunity for AI to boost the effectiveness, accuracy and safety of medical devices, as well as improve quality control in their manufacturing.

AI ENTHUSIASM

In general, how enthusiastic are you about the prospects of AI for your business?



All medtech decision-makers



91%

of medtech decision-makers are enthusiastic about the prospects of AI for their business, with 69% saying they are very enthusiastic.

- Very enthusiastic
- Somewhat enthusiastic
- Not very enthusiastic
- Not at all enthusiastic

*Due to rounding, not all graphs will add up to 100%.



Safety

Safety remains a top priority in medtech and is an area where medtech decision-makers continue to be steadfast in their commitment. While there needs to be prudence in the adoption and implementation of AI, one of the key potential benefits of the technology is that it can make medical devices safer.

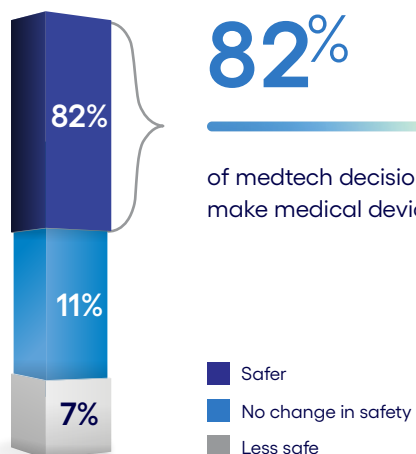
Specifically, medtech decision-makers say AI will enable vast amounts of medical data to be analysed faster and more accurately allowing medtech companies to identify patterns earlier and, therefore, implement improvements or address issues earlier as well. Medtech enabled by AI can help improve the application of protocols and guidelines consistently ensuring stricter adherence to safety regulations.

AI SAFETY

Will incorporating AI into the development and use of these products make them more or less safe?



All medtech decision-makers



82%

of medtech decision-makers believe that AI will make medical devices safer.

- Safer
- No change in safety
- Less safe

AI has the potential to detect early issues and can facilitate timely intervention that prevents complications and improves patient safety.”

– Medtech decision-maker, US

Because AI can analyse vast amounts of medical data and identify patterns that humans might miss which can lead to earlier and more accurate diagnoses.”

– Medtech decision-maker, UK

The use of AI in medical devices enables predictive analytics that can help us anticipate potential problems or complications before they occur.”

– Medtech decision-maker, Germany

AI can follow protocols and guidelines consistently, reducing the variability that can occur with human decision-making.”

– Medtech decision-maker, UK

Even with most medtech decision-makers saying current medical devices are safe, they are always looking for ways to increase safety still further. Medtech decision-makers see significant opportunity in AI helping to do just that, especially through detailed post-market surveillance.

Effectiveness and accuracy

Medtech decision-makers also see the potential for AI to greatly improve the effectiveness and accuracy of medical devices. It can do this by helping to quickly identify patterns, analyse data and automate repetitive tasks. Medtech decision-makers say AI will boost efficiency and effectiveness by decreasing human error, automating patient processes and identifying variations between products.

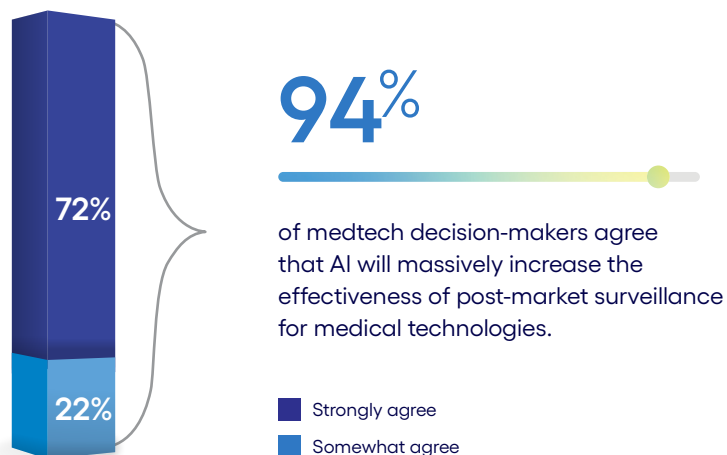
As with safety, one example is **post-market surveillance**, which is a critical tool for medtech companies to ensure their devices remain effective in the real world. AI can help product developers and manufacturers better evaluate data and identify real-world usage and wear patterns. This will ultimately lead to improvements for existing products and can also uncover whitespaces to develop new ones.

EFFECTIVENESS OF POST-MARKET SURVEILLANCE

To what extent do you agree or disagree with the following statement: AI will massively increase the effectiveness of post-market surveillance for medical technologies.



All medtech decision-makers



*Due to rounding, not all graphs will add up to 100%.

AI can personalise safety warnings based on user data and product usage patterns, making them more relevant and effective”

– Medtech decision-maker, US

It can be used to generate effective and detailed reports regarding the safety concerns, potential risks, and consumer response upon usage of the device.”

– Medtech decision-maker, UK

AI can improve the efficiency of the complaint management process and make it easier for customers and the company to communicate.”

– Medtech decision-maker, UK

The usage of AI will increase the efficiency and precision of the product that we are testing for post-market surveillance.”

– Medtech decision-maker, UK

I believe that AI’s ability to minimise human error, increase efficiency and deliver accurate results positions it as a valuable tool in reshaping post-market surveillance.”

– Medtech decision-maker, UK

With the use of artificial intelligence, vast volumes of data from social media platforms, medical records, and devices may be sorted over to find patterns and trends that could raise safety issues more quickly.”

– Medtech decision-maker, UK



AI and Wearble Medtech

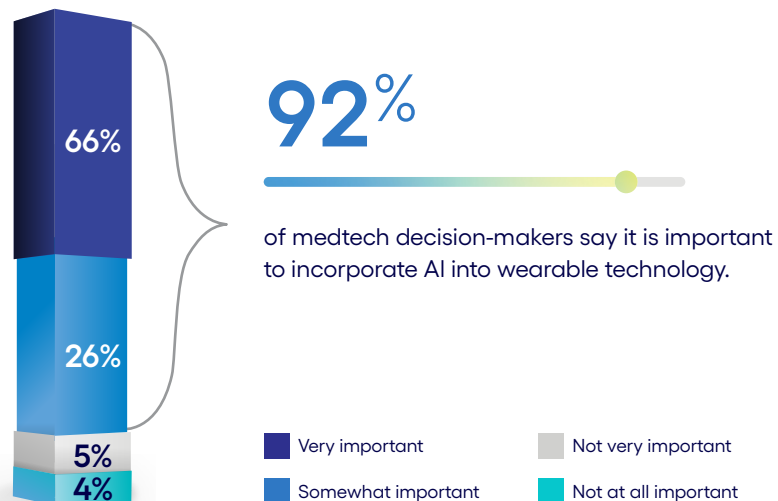
Medtech decision-makers' expectations for increased accuracy of medical devices follow a similar pattern. As **wearable medical technologies** continue to transform the way clinicians manage and monitor patient health, increasing their accuracy will allow medical professionals to better identify abnormalities and enable early detection. AI can play a key role by analysing acquired data to identify technological faults or clinical concerns. Medtech decision-makers strongly believe that integrating AI into wearable technology is the next big step in ensuring and increasing the accuracy of those technologies.

AI IN WEARABLE TECH IMPORTANCE

How important is it that AI be incorporated into wearable devices for customers / patients?



All medtech decision-makers

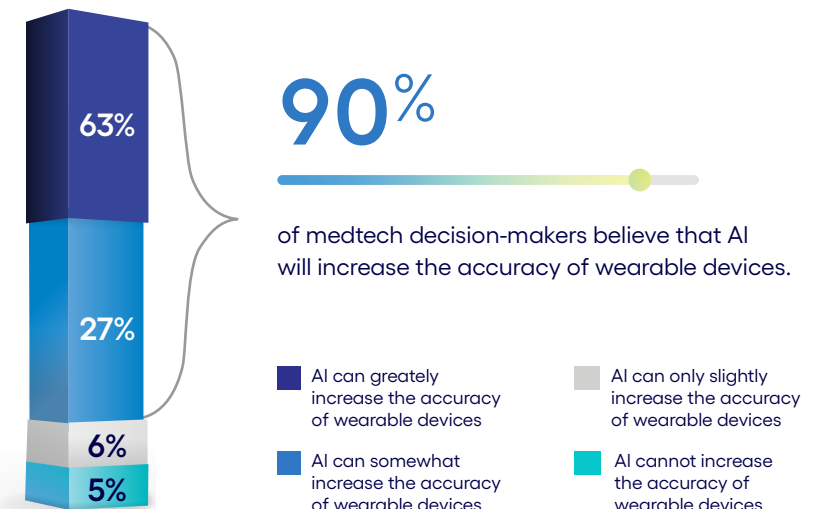


AI AND ACCURACY OF WEARABLES

To what extent can AI help increase the accuracy of wearables for customers / patients?



All medtech decision-makers



Quality control

AI is also expected to improve quality control in manufacturing processes. It can do this by enhancing accuracy and consistency in quality monitoring, as well as by using predictive analytics to anticipate and prevent hardware failures.

AI QUALITY CONTROL INTEREST

How interested are you in using AI for quality control for manufacturing?



All medtech decision-makers



92%

of medtech decision-makers say they are interested in using AI for quality control in manufacturing.

■ Very interested ■ Not very interested
■ Somewhat interested ■ Not at all interested

By automating quality control processes through AI, we can ensure that every medical device meets stringent safety standards, minimising the risk of defects or malfunctions.”

– Medtech decision-maker, US

By integrating AI into quality control, we can easily predict and solve any equipment-related problems by performing predictive analysis to anticipate and prepare for any anomalies or malfunctions that may occur in the equipment later on.”

– Medtech decision-maker, US



AI QUALITY CONTROL IMPACTS

In which ways would AI improve your organisation's quality control for manufacturing?



70%

of medtech decision-makers think AI will improve their organisation's quality control for manufacturing by recognising software defects.

Medtech decision-makers also expect AI to enable more accurate and efficient quality control in **product development and evaluation** by allowing for consistent and automated measurements of new products. As a result, testing will become faster and less prone to human error.

AI IN PRODUCT DEVELOPMENT OUTCOMES

What are the likely outcomes of using AI processes in new product development lifecycles?



76%

of medtech decision-makers anticipate that quality control will be more accurate as a result of using AI processes in new product development lifecycles.



Concerns and Execution Challenges

The road to realising AI's promise is fraught with difficulties.

Despite the expected benefits, almost two-thirds (65%) of medtech decision-makers expressed caution and concern around AI. In particular, they see three main challenges to the effectiveness and speed of AI implementation in the industry: **regulation, data and privacy concerns** and **access to talent**.

Regulation

Globally, the medtech industry faces increasing - and sometimes conflicting - regulatory pressures. With strict and inconsistent regulation between regions already affecting innovation, many medtech decision-makers are uncertain how AI will fit into the mix.

The challenge is that in the safety-critical world of medical device innovation, regulators must strike a delicate balance. In an ideal scenario, regulation protects the public while simultaneously encouraging innovation that delivers significant social benefits. However, if the balance tips too far in either direction, either the public is put at risk or innovation is stifled.

CURRENT REGULATORY ENVIRONMENT AFFECTING INNOVATION

To what extent does the regulatory environment surrounding companies like yours affect innovation in the medtech space?



Overall

78%

of medtech decision-makers believe they are operating in a very or somewhat strict regulatory environment, which is to be expected in such a sensitive area. While more than half (52%) believe it greatly or somewhat boosts innovation, a substantial minority (31%) believe it hinders it.

34%

18%

18%

20%

11%

■ It greatly boost innovation ■ It somewhat boost innovation ■ It does not affect innovation
■ It somewhat hinders innovation ■ It greatly hinders innovation

Importantly, it isn't always the letter of the law that is causing the friction, but rather the logistics of compliance. For example, in **implantable devices**, regulatory challenges reported by medtech decision-makers include:

- Different rules and regulations across countries
- Slow approval processes by regulatory agencies
- Adapting AI systems to new risk classes

To help strike the right balance between protection and innovation, in 2024 European Union (EU) Member States endorsed the world's first comprehensive legal framework regulating AI. This new act describes a variety of regulations that may help with concerns, and mirrors efforts in the US, set out in a presidential Executive Order of October 2023, to establish new standards for AI safety and security.

While these initiatives may also limit the speed of AI implementation and the benefits from innovation in the AI space, they do serve to provide some structure to aim for ([MDDI](#)).

Data quality and privacy

In safety-critical sectors like medical devices particularly, AI also creates concerns around **bias**, ethics, employment and trust. A key focus for regulators, identified by [Pew](#), will be to ensure that the healthcare data employed to train AI is of the highest quality, avoiding biases and ensuring privacy.

AI must avoid biases that cause devices to become less effective (or even dangerous) for sections of the population. To achieve that, AI models must be trained on diverse datasets that accurately reflect the real populations targeted by individual products. However, assembling quality datasets can be expensive and difficult due to fragmented data management and dispersed healthcare systems.

Additionally, there needs to be an assurance of **patient privacy**. Allowing AI to access sensitive data for analysis and training opens the door to a variety of privacy concerns. To avoid these concerns, medtech companies will need to continue navigating complex conversations around the ownership of personal health data.

The impact of data security and privacy will increase, and the likelihood of data loss into the wrong hands will go down.”

– Medtech decision-maker, Ireland

I must ensure that I get my knowledge from trustworthy sources, avoid biases and collaborate with others who have knowledge of languages and data science to help choose, clean and organise this data.”

– Medtech decision-maker, UK

Access to talent

To use AI technologies effectively, and to meet standards and compliance obligations, medtech manufacturers need access to cutting-edge skills and top quality talent.

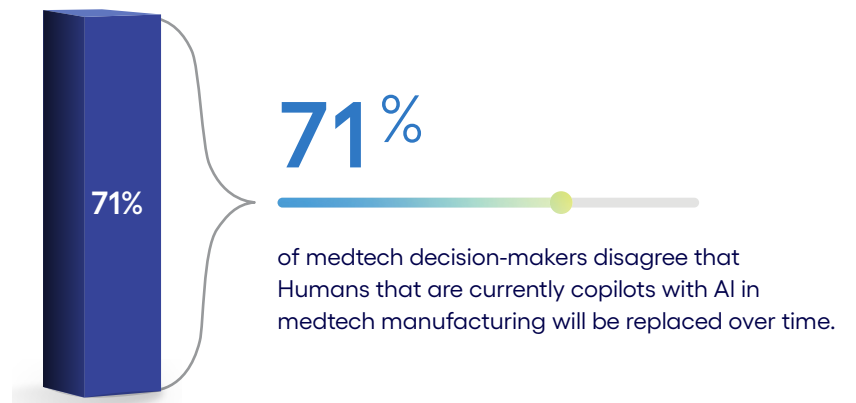
Crucially, human talent will continue to remain in demand even as AI capabilities advance. The majority (71%) of medtech decision-makers say that AI will not replace the humans who are currently working with it.

HUMANS WILL BE REPLACED OVER TIME

To what extent do you agree or disagree with the following statement: Humans that are currently copilots with AI in medical technology manufacturing will be replaced over time.



All medtech decision-makers



Finding that talent will be a challenge, however. The industry continues to face stiff competition for top digital talent, with **Medical Product Outsourcing** magazine identifying AI and automation, cloud computing and data science and analytics among the most in-demand skill clusters for the medtech sector ([MPO](#)). As we'll see in the next section, this means medtech companies will likely need to adopt talent sourcing strategies based on partnering with specialists rather than hiring in-house.



The Road to Success

As the challenges we've highlighted in this report show, medical device manufacturers will need sound strategies for talent sourcing and data foundations if they are to realise the full promise of AI. In doing so they will also demonstrate that they know the regulatory environment well and that they are committed to using AI technologies in a responsible way.

Partnerships are the way to access talent

While it is increasingly clear from our research that AI is the next step for most medtech companies, they lack the in-house resources to quickly, effectively and accurately implement it.

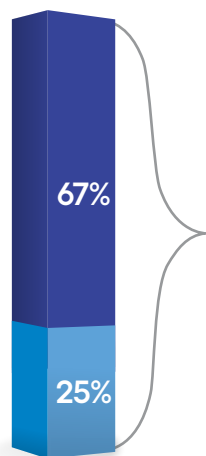
For many, AI is outside their domain of expertise, and they are not afraid to admit they lack the necessary knowledge or capabilities to fully capitalise on its potential. To counter this, the vast majority (92%) of medtech decision-makers are seeking **technology partners** to help them implement and utilise AI to best effect.

SPECIALISTS FOR AI IMPLEMENTATION NEEDS

To what extent do you agree or disagree that specialists (e.g. tech partners, product experts) are needed to effectively implement AI into medical devices / technologies?



All medtech decision-makers



92%

of medtech decision-makers agree that specialists (e.g. tech partners, product experts) are needed to effectively implement AI into medtech.

Strongly agree

Somewhat agree

But while medtech companies are looking for external technology and AI expertise, these aren't the only attributes they seek in a technology partner. Strict regulation and the industry's specific needs mean they can't rely on off-the-shelf, one-size-fits-all AI solutions. Instead, medtech decision-makers will seek technology partners who also have proven medtech domain expertise.

TECH PARTNER CAPABILITIES

Which capabilities of technology partners are important to your business when looking to co-create medtech solutions?



86%

of medtech decision-makers say medical device domain knowledge is important to their business when looking to co-create medtech solutions.

71%

of medtech decision-makers say AI expertise is important to their business when looking to co-create medtech solutions.

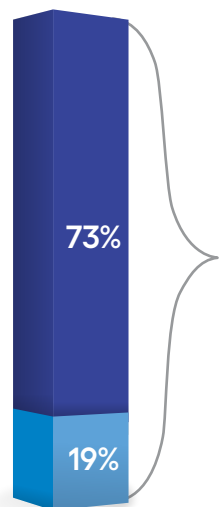
When collaborations between medtech companies and technology/AI partners are established early in the product development lifecycle, it can be beneficial for both parties. A shared knowledge base throughout the R&D process can ensure the product's effectiveness and decrease time to market.

TECH PARTNER IMPORTANCE

To what extent are technology partners important when conceptualising, building and bringing a new medtech to market?



All medtech decision-makers



92%

of medtech decision-makers believe technology partners are important when conceptualising, building and bringing new medical technologies to market.

■ Very important
■ Somewhat important



They can serve as strategic collaborators helping healthcare organisations identify emerging trends to develop new medtech and medicine.”

– Medtech decision-maker, US

Tech partners bring the technical know-how to develop and integrate these technologies.”

– Medtech decision-maker, US

Technology partners bring specialised knowledge and skills essential for developing complex medical technologies.”

– Medtech decision-maker, US

It will be very beneficial for us as it will improve cybersecurity and enhance our research and development capabilities.”

– Medtech decision-maker, UK

The expertise of our technology partners allows us to develop tailored solutions that address unmet healthcare needs, leading to the development of more effective and efficient medical devices.”

– Medtech decision-maker, Germany

With the help of our technology partners, we are able to co-create effective devices that can meet the needs of our consumers and improve patient care.”

– Medtech decision-maker, France

Technology partners will help us boost our innovations, reduce considerable risks to our business in terms of cybercrime and investment, and provide access to state-of-the-art technologies.”

– Medtech decision-maker, UK

Their expertise can unlock valuable insights from vast medical datasets, leading to improved diagnosis, treatment plans and overall patient care.”

– Medtech decision-maker, US

Invest in data strategy and data foundation

The potential of AI lies in its ability to quickly and accurately process vast amounts of data. Investing in a data strategy to build the right data foundation is therefore critical to ensuring effective use of AI.

Medtech decision-makers are confident in AI's ability to analyse and leverage large amounts of data, but few consider themselves to be mature in terms of their ability to house such large datasets. Only 17% consider their company to be a "Digital Native" with a primarily or entirely digitally-driven business model.

However, at the same time, 97% believe the medtech industry as a whole is handling patient data well. This misalignment means either that medtech decision-makers see their own company as a laggard, or that they are overconfident in the industry's ability to overcome the data challenges it faces. In either case, it's a sign that action is needed.

Large-scale data processing and device connectivity, crucial for bringing medtech to a wider market."

– Medtech decision-maker, UK

It can identify any safety concerns by analysing enormous volumes of data."

– Medtech decision-maker, US

AI enables considerably faster decision-making than humans by analysing massive volumes of data from several sources."

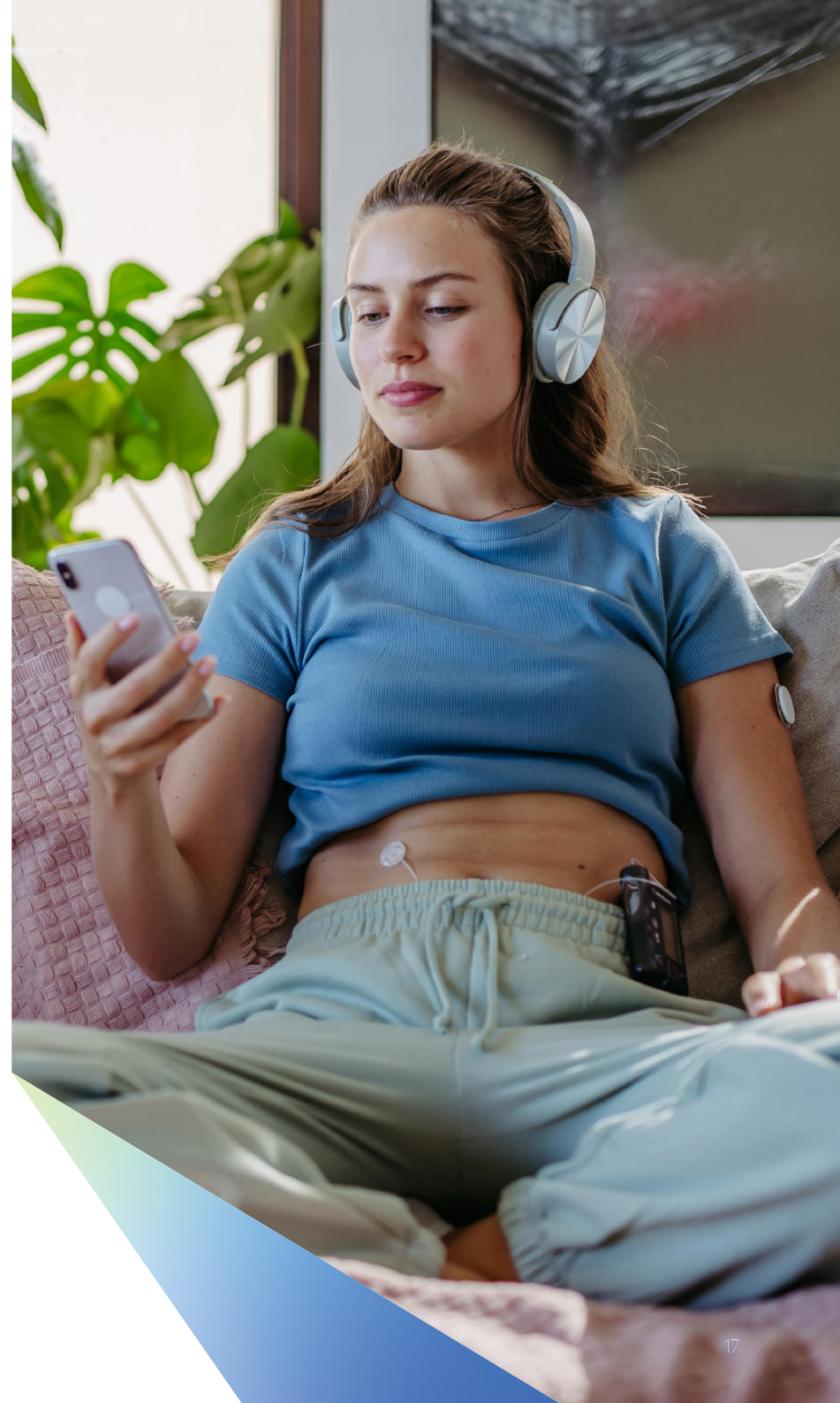
– Medtech decision-maker, US

Large volumes of medical data can be analysed by AI to find trends and abnormalities that individuals would have missed, thereby resulting in earlier and more precise diagnoses."

– Medtech decision-maker, UK

Large datasets containing subtle patterns or correlations that can point to new safety problems can be detected by AI algorithms, enabling early discovery and inquiry."

– Medtech decision-maker, UK



Human copilots are crucial to advancing medtech

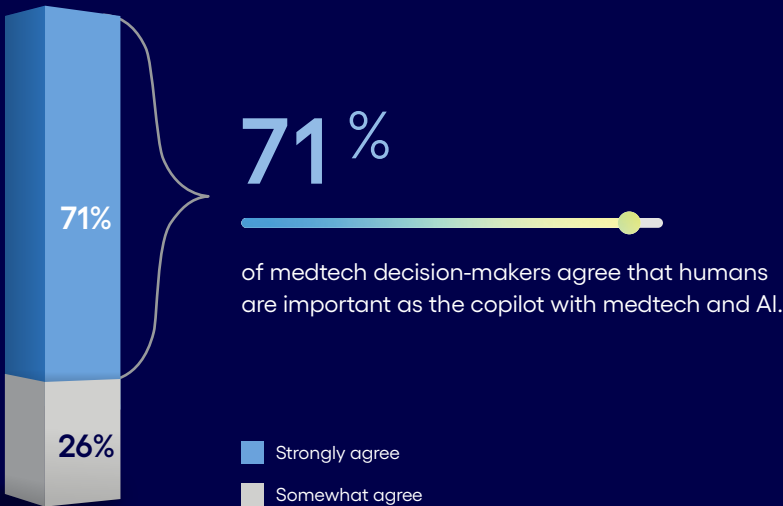
Overall, the key to ensuring sustained enthusiasm, optimal productivity and the ability to navigate future challenges is finding a balance between AI and human oversight. AI cannot simply take over. A **copilot model** allows the best of both worlds, with humans providing creativity, empathy and nuanced judgement and understanding, while AI focuses on its core strengths of data processing, identifying trends and repetitive tasks. AI must therefore be infused into existing processes to expand human capabilities.

STATE OF AI – HUMAN ROLE

To what extent do you agree or disagree with the following statement as it relates to your industry: Humans are important as the copilot with medtech and AI.



All medtech decision-makers





Conclusion and next steps

There is immense opportunity for medtech companies to be more innovative in their use of AI to improve human health and wellbeing. The industry is moving to implement AI into products and processes with vigour, balanced with appropriate caution. There are undoubtedly challenges ahead, but they do not outweigh the potential benefits.

The next steps for medtech companies should be to assess their current state, pilot specific AI use-cases relevant to them and, in parallel, plan for scaling AI responsibly. With decision-makers from leading companies reporting high levels of excitement and a clear desire to embrace AI, now is a good time for all medtech companies to begin adoption in earnest or risk falling behind.

Methodology

Cognizant and Microsoft commissioned a quantitative survey with decision-makers in the medical technologies sector in the US and Europe (France, Germany, Ireland and the United Kingdom). 200 decision-makers were involved in this study, at a range of levels within their organisations.

Medical technology decision-makers are defined as professionals who work in the medical technologies sector (Diagnostics Molecular Diagnostics, Medical Products/ Devices, Pharmaceuticals Biotechnology) in companies with annual revenues of \$500 million+ / £385 million+. They are involved in decisions on which technology service providers and consultants their company or unit uses. They are the most senior person or direct report to the most senior person in their respective lines of business.

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