Digital Health and MedTech

New Signals for Transformation

Globally, healthcare is experiencing unprecedented pressure and disruption. Today's challenges range from affordability issues to shifting patient expectations. Costs continue to rise. Pressure is mounting to find innovative solutions. The healthcare ecosystem must help alleviate these concerns. MedTech and Pharma are under pressure to improve R&D, service models and treatment. The goal is to reshape the industry with a modern approach that involves digital technology. And one that delivers significantly more ambulatory and at-home care.

There are clear benefits to digital innovation. However, it's important to know the forces behind its adoption. And it's essential to understand what challenges stand in the way. We wanted to gain a deeper understanding of this topic. To do so, we interviewed over 30 Digital Health senior executives and C-Suite leaders from across the MedTech and Pharma sectors. Interviews were primarily conducted with members of AdvaMed's Digital Health Center of Excellence.

To gain a deeper understanding, we interviewed 30 Digital Health senior executives and C-Suite leaders from the MedTech and pharma sector in AdvaMed's Digital Health Center of Excellence. In addition, we surveyed 150 MedTech senior executives globally and analyzed over 100 M&A deals and over 600 product launches from a subset of MedTech companies that took place between January 2019 and May 2022. In doing so, we found that five key trends are driving the future growth of MedTech.

**Five trends will help MedTech transform healthcare through Digital Health.
If approached strategically, customers - patients and providers - will experience better outcomes.**

Trend 1:
The Consumer Patient

Healthcare is no longer a one-way interaction where the patient is on the receiving end. Rather, it is now a structure of continuous engagement. Here, the patient becomes the consumer. They actively demand and receive healthcare consistent with their broader expectations for non-healthcare services.

Trend 2:
Care Anywhere, Everywhere

The Consumer Patient is demanding care anywhere and everywhere. In response, healthcare is increasingly expanding in scope. It's moving from the traditional setting of hospitals to ambulatory and at-home care.

Trend 3:
The Rise of Digital Health

Healthcare is shifting to anywhere and everywhere. Because of this, the Digital Health agenda has now become a priority for the C-suite. It's used to continuously generate insights. And it powers the expansion of services and products throughout patient care pathways.

Trend 4:
Converging Sectors

The rise of digital in healthcare is fueling non-traditional deals. Now, various sectors are converging. They're coming together to develop products and services. And they're doing this across the entire care pathway.

Trend 5:
New Regulatory Pathways

Digital Health and the digitization of health may very well fall outside the bounds of established regulatory pathways. This is particularly true for any untested technologies used. As a result, new approaches from the sector may be required to help ensure the success of Digital Health.

Across the board, we've heard that MedTech leaders are shifting their businesses. They're moving from traditional models of healthcare and adopting Digital Health as a core part of their approach to improving patient outcomes. Consistently, executives reported that they are grappling with major challenges such as payers not being caught up with the power of the Consumer Patient.

The industry is still working on solutions. The aim is to generate evidence on a more compressed but still acceptable timeline. Meanwhile, companies are considering how to market, sell and create consistency with their brands. At the same time, they're constantly adjusting to evolving regulatory pathways.

Traditional 10 to 15 year timelines to launch a new clinically-proven product are less viable given the pace of technology and consumer expectations. The industry is in flux. All leaders in our research agree that MedTech must find a new approach, and it must reflect and benefit from the speed of transformation enabled by digital innovation.

The solution clearly sits within Digital Health. Most respondents reported that momentum is growing and they believe that Digital Health adoption is inevitable. But, we have to ask:

Is this the moment that digital health moves from pilots to scalable transformation? How will the industry find success? How should MedTech respond to these emerging trends? And what needs to change to realize the potential of Digital Health?

How the five trends are
impacting MedTech companies

Trend 1:
The Consumer Patient

We're seeing the rapid growth of digital technology in every industry across the world. It's set a standard in how consumers expect to experience and interact with medical technology. It's vital MedTech companies are able to go beyond the standard expected. This is how they can help ensure successful healthcare delivery.

People no longer anticipate healthcare as being a one-way, one-size-fits-all transaction. Rather, they're demanding a combination of factors. This is to allow for continuous engagement in how people manage their wellness. And they want to be treated safely, equally and with understanding.

This is what we refer to as the Consumer Patient.

Trend 1: The Consumer Patient

The Consumer Patient has better health literacy. They are in more control of their health than previous generations. This can be an asset to MedTech companies. However, it requires many companies to re-orient their long-term strategies. They must shift from a "product first" to an "outcomes first" mindset.

It also shifts a bulk of the responsibility for risk from institutions to the patient. According to Accenture's 2021 Global Digital Health survey of cross-industry C-Suite executives, a majority of the 350 respondents agreed that Digital Health accelerates the shifting of risk from employers and governments to individuals.[1]

> 70%

of respondents said that the Consumer Patient phenomenon is very relevant. They expect it to significantly re-orient their firms' long-term strategies.[2]

Healthcare consumers are becoming more demanding. They're also taking more control of their health. And together with their physicians, they're becoming more involved in decision-making. This is leading to increased importance in the consumer/physician experience. Not to be overlooked in this transition is the increasing pressure on physicians to adopt digital tools.

Many physicians are already experiencing heightened workloads. They are now being asked to log into different portals for different products. And they're expected to learn the software and how the tools operate and fold all of this information into their services. Some form of standardization of Health Care Professional (HCP) digital tools is needed. Without it, this experience will remain unmanageable. It has led many MedTech experts we spoke with to validate the shift to an "outcomes-first" mindset.

For the majority of companies, the focus used to be on developing next-generation products with an engineering mindset. Now, they are looking at entire care pathways, identifying challenges for physicians and patients. A big part of this is designing better experiences and products that fit into both physician workflows and consumer lifestyles. In doing so, they're looking to create increased value. And they're trying to drive better outcomes across the ecosystem.

The rise of the Consumer Patient requires MedTech companies to adopt and develop human-centric approaches. At the same time, patients are also becoming increasingly more powerful. They now have the ability to self-educate. And they have expectations toward effective treatments and the immediacy of care. Leaders in our interviews pointed to the need for specialized skills and expertise in this area. These will be core to meeting patients' expectations.

Trend 1: **The Consumer Patient** — Challenges to overcome

Digital Health products need human-centric design. They must be built for integration with other products, services and platforms. They must be implementable. And they should always be convenient and easy to operate. This will help MedTech companies make sure their desired outcomes are always successful. However, it should be noted that human-centric design requires a significant level of effort to achieve. Amazon, for example, has 10,000 employees alone working on its Alexa products and services.[3]

A lot of MedTech products fail due to the lack of the 'outcomes' mindset. They go 'product-first' vs. 'value/outcomes-first'.
AdvaMed Digital Health CoE Executive

Some successful MedTech companies are approaching the challenge by prioritizing the hiring of high-quality digital talent with consumer product experience. They then teach their talent how to operate within the MedTech space. This approach is an attempt to account for digital and human-centric expertise. Both of these are needed to drive success in this space.

When done well, this approach can support product and engineering teams. It enables them to focus on innovation. And it gives space for a surge of ideas. Many of these ideas often end up on the floor. This is typically due to time-constraints or limited capacity.

Developing the right connected programs for customers remains a hurdle. This is true in terms of programs for both patients and providers. There are many challenges across MedTech categories. We found that 46% of executives agreed that "implementation complexity" and "not having the right partners" are their primary challenges.

This is important. 51% of all respondents reported they believed that the customer's voice needs to be strengthened. They know it's the key to improving the Consumer Patient relationship. Customer service capabilities followed closely behind with 49%.[4]

Key takeaways:

(1) Patients are taking more control of their healthcare experiences. They're demanding continuous engagement. And they're gaining a better understanding of their health.

(2) MedTech leaders believe that the consumer patient is very relevant. They expect it to significantly re-orient their firms' long-term strategies.

(3) The goal is to effectively serve the Consumer Patient. To do this, MedTech companies need to design new tools and solutions. And they must fit both physician workflows and consumer lifestyles.

How the five trends are
impacting MedTech companies

Trend 2:
Care Anywhere, Everywhere

The Consumer Patient is increasingly demanding services in both remote and digital settings. Because of this, healthcare is expanding. It's now moving from hospitals to ambulatory and at-home care. The change was accelerated by the emergence of COVID-19. The pandemic amplified the demand and need for virtual care and remote patient monitoring.

In 2020, just prior to the pandemic, only 7% of people participated in a virtual consultation with a healthcare provider. In comparison, 32% used virtual consultations in 2021. And compared to Accenture's last pre-pandemic survey, remote patient monitoring tripled during the same period.[5]

Healthcare has become a full-time part of a person's life. It goes where they go. It is no longer episodic, contained healthcare experiences. **This decentralization trend is something we refer to as Care Anywhere, Everywhere.**

Trend 2: Care Anywhere, Everywhere

One MedTech Executive leading a Virtual Care Business Unit stated, "All COVID did was change the face time—it did not transform the workflow of the clinic." Healthcare has become more digital and remote. However, the industry remains at the beginning stages of building the right platforms and capabilities to meet the needs of the Consumer. Patient.

The decentralization of healthcare will require new business models. They must include new products and solution strategies. This is vital to service the full care continuum. The new models should also feature different marketing strategies. And they should target various types of consumers, such as hospitals, physicians and patients. It's also advisable to make use of changing sales team incentives.

In our survey, we asked 150 MedTech executives to rank the changing care settings in order of importance based on their business goals.[6] This was the result:

1. Remote devices and monitoring
2. Preventative care (wearables)
3. Telehealth

Executives confirmed that the decentralization of healthcare impacts their businesses. And remote devices and monitoring technologies are having the biggest impact so far. Over 75% of executives surveyed expect expanding care settings and delivery

models to significantly re-orient their company's long-term strategy. They believe these changes will require them to completely rethink their business approach.

In fact, approvals for patient monitoring products in the US were 60% higher during the 18-month period between July 2020 and Dec 2021 compared to the 18-month period prior.[7, 8]

Fig 1: 510k approvals for patient monitoring products

Period	Approvals
01/2019 – 06/2020	83
07/2020 – 12/2021	121

+60%

Source: Accenture Research analysis of 510k approvals, 2022, Global Data database

The majority of MedTech experts we interviewed confirmed their traditional products are driving the bulk of their revenues. However, they also noted they see this expansion of care to new settings as part of their growth strategy. For example, smaller, connected instruments with rapid diagnostic tests are being placed in physician's offices instead of large hospital labs. Similarly, at-home tests with virtual assistance have become very common due to the pandemic.

Trend 2: Care Anywhere, Everywhere

In orthodontics, patients are now using progressive trays instead of traditional braces. This helps them avoid the back and forth of going to the orthodontist's office. It also enables orthodontists to double their treatment capacity. And it saves patients countless hours spent on treatment. We can also look to neuromonitoring devices. These can be remotely reprogrammed as necessary. They save time for many patients. And they were especially common during the pandemic.

"We estimate that 80% to 90% of chronic and behavioral care can shift to virtual. It means that providers are able to work to the full extent of their medical training, rather than burning time on more menial tasks."
AdvaMed Digital Health CoE Executive

At-home diagnostics, like wearables, also allow patients to capture data. They enable new opportunities to capture data that don't necessarily coincide with hospital visits. Wearables help physicians gain a deeper understanding of their patients. And they can help determine when potential required interventions will be needed, which can save further costs and time.

Trend 2: Care Anywhere, Everywhere — Challenges to overcome

It's time to move products from hospital settings to alternative settings such as physician's offices, ambulatory centers or at-home care. But this move has implications on the business models of MedTech companies. And the shift requires comprehensive solutions. They are critical to solving any new challenges that may arise.

Different payment and contracting models will be impacted. These impacts will also have implications for the size and incentives of sales teams. For example, consider the large diagnostic instruments that may be sold with a five to ten-year contract to large hospitals. Alternatively, small rapid test instruments could be sold to thousands of physicians' offices. Likewise, at-home tests can be sold to millions of consumers.

Many executives report that many MedTech companies are bolting on their old structures to create Digital Health teams by simply identifying and re-labeling team members. This results in a lost opportunity to enrich home-grown expertise with new ideas and ways of working. It's advisable to blend and incubate external talent in addition to upskilling and reskilling existing talent.

Digital Health requires the addition of talent focused on design and technology. And it must be partnered with the best of MedTech's core competencies. These are engineering, regulatory and therapeutic area knowledge. Digital Health should transition from being (in many cases) a small fringe group into part of a more comprehensive strategy for the future.

Marketing is also different when it comes to Digital Health. Traditionally, MedTech companies have access to disease area specialists. For example, orthopedics, cardiologists, oncologists and more. The decentralization of healthcare, by its nature, requires access to consumers and primary care physicians. It requires MedTech companies to build new relationships. They must leverage different thinking and mindsets for marketing teams.

It's clear that the broad action to be taken in Care Anywhere, Everywhere is in the designing and engineering of technology that supports decentralized care. It is not simply an overlay of Digital Health teams to existing structures. Instead, it's an integrated approach. And it's designed around patients and physicians requiring MedTech to develop new business models.

Key takeaways:

1. Healthcare is expanding from hospitals to ambulatory and at-home care.

2. Many executives agree that the industry remains at the beginning stages of having the capabilities to meet decentralized care.

3. Decentralized care requires the addition of talent focused on design and technology. It must be partnered with the best of MedTech's core competencies: engineering, regulatory and therapeutic area knowledge.

How the five trends are
impacting MedTech companies

Trend 3:
The Rise of
Digital Health

Healthcare is shifting anywhere and everywhere. As a result, Digital Health strategies born in the C-suite have become a priority. They're needed to generate insights and they're key to expanding services and products throughout patient care pathways.

99% of survey respondents said that the development and commercialization of Digital Health solutions has accelerated in the past two years. As part of this, companies now require various new and strengthened capabilities. They're essential to the execution of their visions.[9]

This is what we call the Rise of Digital Health.

Trend 3: The Rise of Digital Health

In terms of the primary strategies for digital expansion, respondents reported being evenly split. **Build (44%)** is a traditional way to build digital health capabilities in-house. It requires companies to make investments in R&D, technology, MedTech and new business models.

Buy (47%) involves asset acquisitions. They enable companies to expand their pipeline across therapeutic areas. They also help companies to add capabilities to innovate faster or reach customers in new ways (less than 10% reported primarily pursuing a hybrid model of the two).[10]

As part of the investments for the Build model, MedTech companies are increasing the amount of their Digital Health spend within their R&D budget. Most expect it to increase over the next three years. Today, these companies spend an average of 5% of their R&D budget on Digital Health.[11] Within three years, they expect that to be 12%.[12]

In our analysis of over 600 product launches between January 2019 and May 2022, just over a quarter have been Digital Health products. During that time, diagnostic imaging has been the biggest category.[13]

As part of the Buy model, MedTech companies have also been inorganically growing their Digital Health products and offerings. In the past three years, for the 25 companies we analyzed, almost half of Mergers and Acquisitions (M&A) deals were in the Digital Health space. During this time, robotics, remote monitoring and decision support tools made up the vast majority of deals.[14]

MedTech companies are sticking with their core competencies. But they're also partnering with other companies to strengthen their portfolio. The real end-to-end vision is multi-dimensional. And it includes when, where and to whom insights are connected to during the patient journey. All of this can potentially reveal surprising and actionable next steps for care.

Why are MedTech companies executing M&A deals?

Respondents identified the following factors as drivers to invest in Digital Health capabilities:[15]

Research supplies and equipment:
expanding geographic reach

Therapeutic area devices:
obtaining new inventions or assets

Imaging:
building organizational and internal capabilities

Medical services and monitoring:
expanding geographic reach

Trend 3: The Rise of Digital Health

With increased investment in digital via R&D and M&A, a comprehensive plan is key to building capabilities. MedTech executives feel confident in their M&A abilities and they're confident in their R&D and manufacturing capabilities. However, our survey suggests most companies need to develop a better understanding of the market and customer behaviors and expectations. These are essential to keep up with the Consumer Patient and serve them in various care settings.

> 75 %

of respondents said they now have capabilities for internal R&D tech—such as Internet of Things (IoT), analytics and other MedTech—strong M&A capacity and Digital Health manufacturing. However, more than half also reported that IoT, omni-channel marketing, customer expertise, market intelligence and manufacturing still require further development.[16]

In addition, according to the experts we interviewed, a good strategy of integration post-acquisition is also key. This is where acquired capabilities are scaled across the entire portfolio.

Trend 3: **The Rise of Digital Health** — Challenges to overcome

The common vision for Digital Health is for it to be able to reveal insights. Insights must be surprising, individually relevant, not generically true and valued by the health ecosystem—and increasingly the consumer patient. In most cases, companies are less interested in innovating ways to gather data. Instead, they are focusing more on what they can do with the data.

One major barrier has been fragmented data or not having access to data. For example, almost every hospital has different rules and approaches to risk-taking. This is typically because there is no central guidance on what's appropriate or acceptable to share.

Experts we interviewed pointed to the need for a dialogue among the MedTech players, hospitals and governments. They must work together to form an overarching guideline on data privacy. This is how they can enable Digital Health products and services while protecting the individual's data. It's key for serving the healthcare consumer across the whole care pathway.

It enables all biopharma, device and lifestyle interventions to be connected and personalized to set up the best possible outcomes.

> Several respondents believe that there are crucial datasets that have still not been fully unlocked, such as voice, text and video data. If companies can extract key insights from those and act on them, they may be able to deliver more comprehensive and better care.[17]

Transparency and education of consumers are also very important. We have seen this in previous years. Indeed, one reason many people didn't adopt Digital Health technologies more broadly before was due to an attempt to safeguard personal health information. Fortunately, respondents report they would be more likely to adopt digital technologies if they felt more confident in data security and privacy (30%) and if these technologies enabled them to receive better information about their health (30%).[18]

A major opportunity many executives highlighted is that Digital Health may help physicians unlock new insights. It can do this by adjusting their approach, including expanding beyond the clinical workflow to include at-home patient data. They also need to trust that the data collected is accurate, safe and secure. This is essential in order for them to adopt Digital Health more meaningfully.

Executives in our survey found that the biggest challenge they face is getting clinicians to understand how Digital Health benefits them. For the most part, they want hard evidence. This requires clear communication, evidenced clinical studies, white papers, and other data that they can clearly see. Once they have this information, they are more likely to adopt Digital Health.

Trend 3: **The Rise of Digital Health** — Challenges to overcome

Key takeaways:

1 99% of respondents indicated that development and commercialization of Digital Health solutions has accelerated in the past two years. As part of this, companies require various new and strengthened capabilities to execute their visions.

2 Patients and health professionals need to trust that data collected is accurate, safe and secure in order for them to feel comfortable using it.

3 Fragmented data or lack of access to data has been a barrier to development. An overarching guideline on data privacy is needed.

How the five trends are impacting MedTech companies

Trend 4: Converging Sectors

Historically, MedTech and other industries have largely been siloed and they have experienced different levels of success when entering the domain of each other. Solving this issue requires evolving to a much more innovative approach. It must include a full end-to-end solution and be comprised of many partners, verticals and companies.

The burden to provide the total solution doesn't fall on individual companies alone. However, they do need to be part of the connected solution. As we've seen, various industries are coming together to develop products and services across the entire care pathway.

This is leading to non-traditional deals and partnerships, or Converging Sectors.
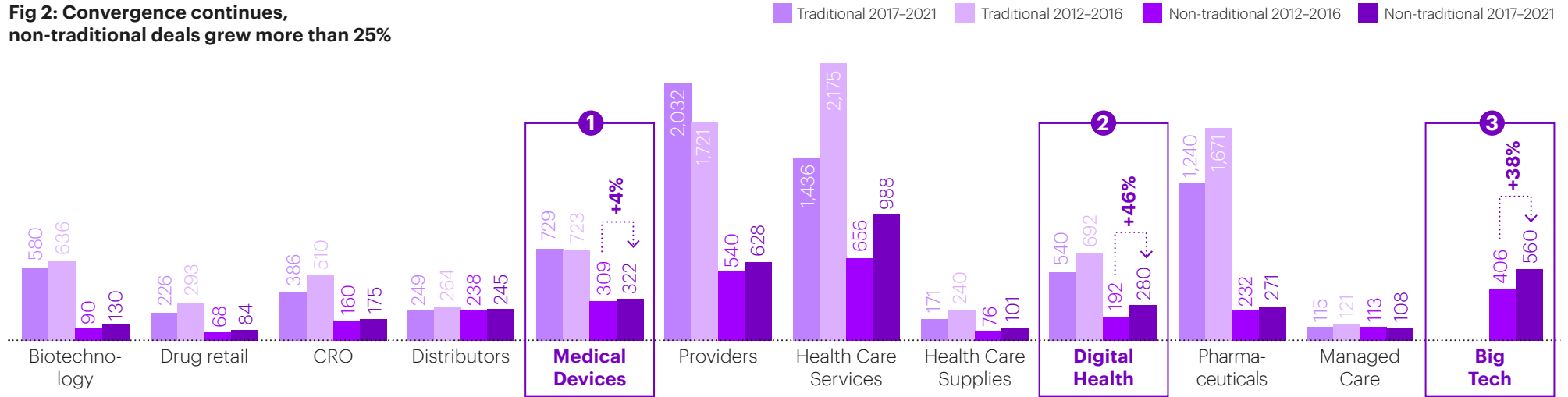
Trend 4: Converging Sectors

To understand healthcare sector convergence, we analyzed all mergers, acquisitions, private placements and majority equity stake deals over a ten-year period between 2012 to 2021. All buyers and sellers of life science and healthcare-related deals as designated by S&P's Capital IQ database were considered. Deals within a sector are considered "traditional," whereas deals between sectors are considered "non-traditional." [19]

> 86 %

of respondents agreed that future success will depend on companies targeting the entire care pathway rather than specific products and services.[20]

Fig 2: Convergence continues, non-traditional deals grew more than 25%

Legend: ■ Traditional 2017–2021 ■ Traditional 2012–2016 ■ Non-traditional 2012–2016 ■ Non-traditional 2017–2021

Chart data by sector:

Sector	Traditional 2017–2021	Traditional 2012–2016	Non-traditional 2012–2016	Non-traditional 2017–2021
Biotechnology	580	636	90	130
Drug retail	226	293	68	84
CRO	386	510	160	175
Distributors	249	264	238	245
Medical Devices ①	729	723	309	322 (+4%)
Providers	2,032	1,721	540	628
Health Care Services	1,436	2,175	656	988
Health Care Supplies	171	240	76	101
Digital Health ②	540	692	192	280 (+46%)
Pharmaceuticals	1,240	1,671	232	271
Managed Care	115	121	113	108
Big Tech ③	—	—	406	560 (+38%)

① While med-device non-traditional deals didn't grow, the most frequently targeted sector was digital health (30%)

② Digital health convergence grew 46% in the past five years, and 12% of the convergence is with the med-device sector

③ Big tech companies are increasingly getting into healthcare with 38% growth
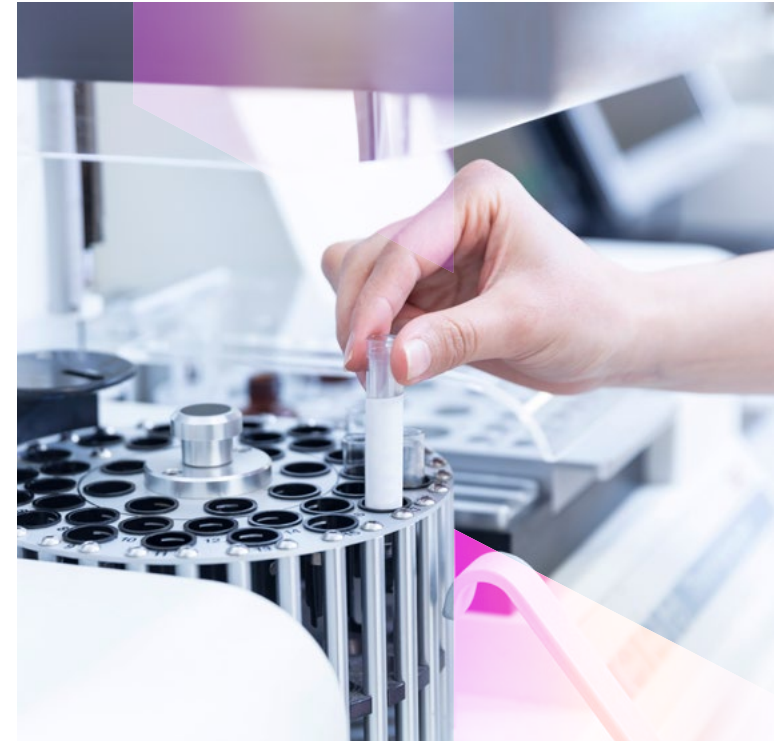
Trend 4: Converging Sectors

Approximately 30% of deals within Medical Device and Digital Health segments are non-traditional. This indicates that MedTech is breaking out of its historically conservative reputation. It is now embracing digital innovation and the MedTech sector has been placed at the forefront. It currently is driving massive investment across the spectrum. Within MedTech non-traditional deals, the most frequently targeted sector was Digital Health, which made up roughly 33% of such deals.

All large players, such as Philips, Baxter, Medtronic, and Smith & Nephew, have leveraged deals with digital health companies. They've done this specifically to boost their portfolios. For instance, Baxter acquired healthcare software developer True Process to strengthen its personalized care offerings and Philips has acquired over 13 MedTech companies in the past five years. With these acquisitions, it can grow its connected care business to transform the delivery of healthcare with integrated solutions.[21]

In the Digital Health segment, more than half of the nontraditional transactions in the past five years have been with healthcare services companies and 12% have been with medical device companies. For instance, Planet DDS is a provider of practice management software systems to the dental industry. It acquired Apteryx, a company engaged in developing and commercializing dental devices and related software, in 2021 for $30 million.[22]

As compared to the period between 2012 and 2016, there were no notable changes in MedTech non-traditional transaction volume.

However, the share of convergence with the Digital Health segment grew from 19% to 33% in the last five years. At the same time, non-traditional Digital Health segment deals registered more than 45% growth.

Trend 4: Converging Sectors

This is primarily due to an increase in deals with healthcare services, MedTech companies, providers and biotechnology companies. Overall, large tech deals grew by 38%. The majority of deals were in Application Software, IT Consulting, and Electronic Equipment and Instruments.[23]

Pharmaceutical sector companies are also converging in deals with other segments. They're using the deals to greatly expand their portfolios. In the past five years, more than 20% of non-traditional biopharma deals were with the MedTech segment.

In 2017, Allergan plc, a biopharmaceutical company, acquired ZELTIQ® Aesthetics, Inc., a medical technology company behind a proprietary-controlled, cooling fat-reducing treatment, CoolSculpting, for $2.4 billion. Such unconventional deals help strengthen biopharma companies' portfolios by entering adjacent areas in the care continuum.[24]

Throughout our interviews, we heard a common theme; MedTech executives see pharma as future customers. This will occur as companies build connected infrastructure to bring meaning to data. For example, Dako (part of Agilent) and Merck & Co. collaborated on developing a companion diagnostic test. It enables the analysis of the potential tumor biomarker PD-L1 to aid in the treatment of cancer.

Dako's PD-L1 test is approved by the FDA as a companion diagnostic to Merck's Keytruda treatment for various indications. In addition, Dexcom, a glucose monitoring device company, collaborated with biopharma company Eli Lilly. They're working together to help improve diabetes management for patients. Their solution helps quickly identify adult patients who struggle to manage their postprandial glucose levels. It also helps determine if patients may benefit from treatments like Lyumjev from Eli Lilly.

The top drivers for cross-industry convergence and partnerships to advance Digital Health vary among sectors:[25]

Research supplies and equipment:
government and biotechs

Therapeutic area devices:
large tech companies

Imaging:
large tech and insurers

Medical services and monitoring:
large tech and government

Trend 4: **Converging Sectors** — Challenges to overcome

As indicated in the high number of non-traditional deals, everyone has a role in the Digital Health ecosystem. Because of this, companies need to consider partnering within the broader ecosystem. This must be done in addition to M&A.

Respondents reported that a common motivation for collaborations is a partner being able to bring products to market faster. They also highlighted the need for collaborations to develop differentiated products that they couldn't develop alone. They noted that the key to the most successful partnerships is balancing varying risk tolerances. These include regulatory and reputational risk, between partners and being mindful of cultural differences.

87 %

of respondents identified government regulations as a threat and disruptor to their business. This may be due to the shifting nature of regulatory guidelines as regulatory bodies work to keep up with the rate of new and emerging technologies and help ensure they are safe and effective for those they are trying to support.[26]

One of the biggest challenges MedTech companies face when going into partnerships is ensuring their potential partner has the required level of data privacy and protection compliance. However, evaluating companies that have historically operated outside of varying data privacy and protection guidelines (GDPR and HIPAA) can be tricky.

A lot of time and resources are spent investigating and determining if a potential future partner meets the level of data security they are comfortable with. A standard global definition of levels of data privacy compliance would save industry partners time and resources and it would enable them to make products and solutions available to patients faster.

Key takeaways:

(1) Industries are coming together to develop products and services across the entire care pathway, which is leading to non-traditional deals and partnerships.

(2) Approximately 30% of deals within the MedTech and Digital Health segments are non-traditional, indicating that MedTech is breaking out of its historically conservative reputation and embracing digital innovation.

(3) Key to the most successful partnerships is balancing varying risk tolerances. It should include regulatory and reputational risk, between partners and being mindful of cultural differences.

(4) A standard global definition of levels of data privacy compliance would save industry partners time and resources. And it would enable them to make products and solutions available to patients faster.

How the five trends are
impacting MedTech companies

Trend 5:
New Regulatory Pathways

Digital Health sits at the convergence of medicine and technology. It's precisely due to this positioning that it is governed by a number of different regulatory and legal frameworks and working groups within governing bodies. However, the focus throughout remains on helping ensure that human health and consumer interests are well protected. This largely happens through regulation and enforcement.

As such, companies need to be able to navigate the New Regulatory Pathways.

Trend 5: New Regulatory Pathways

Digital Health sits at the convergence of medicine and technology. It's precisely due to this positioning that it is governed by a number of different regulatory and legal frameworks and working groups within governing bodies. However, the focus throughout remains on helping ensure that human health and consumer interests are well protected. This largely happens through regulation and enforcement. As such, companies need to be able to navigate the New Regulatory Pathways.

In nearly every part of the world, there has been a surge in the adoption of software in healthcare settings. The surge was driven by the emergence of COVID-19. Most, but not all software in healthcare settings is classified as Software as a Medical Device (SaMD).[27]

The International Medical Device Regulators Forum (IMDRF) is a consortium of medical device regulators from around the world. It defines SaMD as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device." In the US, the Food and Drug Administration (FDA) largely follows this definition.

The FDA is also working to establish a new regulatory framework. It will adopt a risk-based approach.

In China, SaMD is classified as a Class II or Class III device by the National Medical Products Administration (NMPA). It is subject to premarket authorizations. Software technologies are rapidly changing. As a result, China also released the draft amendment of the technical review guidelines for SaMDs in 2020.[28]

Inside the EU, Digital Health's legal environment is very diverse. In 2021, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) developed the "Software and AI as a Medical Device Change Programme." It provides a regulatory framework and is seeking changes across the SaMD lifecycle. These changes range from qualification to classification to pre- and post-market requirements.[29]

Adaptive artificial intelligence (AI) technology is another key component of Digital Health. AI is also constantly evolving and changing and it brings its own challenges to existing regulatory frameworks. In response, the EU published its proposal for the Artificial Intelligence Regulation. It opts for a risk-based approach for AI systems.[30]

Our experts voiced that in many cases, when it comes to regulatory bodies and advancing Digital Health, agencies are under-resourced to handle the volume of cases. Governing bodies are strained to move at speed. This lack of urgency is resulting in high opportunity and resource costs for Digital Health innovators.

Trend 5: New Regulatory Pathways — Challenges to overcome

Our survey shows that MedTech executives ranked regulatory uncertainty as a medium-high barrier. They agreed that this has a moderate impact on their Digital Health agenda. Regulatory bodies have established guidelines. But they remain at a very high level and fail to address the intricacies of Digital Health solutions that are rapidly being developed. A harmonized set of guidance and regulatory frameworks is essential to support innovation and help ensure the safety and effectiveness of solutions.

However, across the board from our interviews and surveys, we heard a common theme that MedTech is navigating barriers within regulatory. Surprisingly, only 26% of respondents indicated that regulatory uncertainty had a "high or great impact" on their Digital Health agenda.[31]

Given the current state of regulatory guidance, experts in our research pointed to the importance of the mindset shift when it comes to thinking about regulations and receiving approvals for their Digital Health products. In the past, they thought more about the minimum evidence required to receive approval for their devices.

Now, there is a better approach; they should ask, "How can I ensure this product is safe and effective for healthcare consumers?"

This parallels the shifting mindset of "product-first" to "outcomes-first." And it underlines the importance of putting the consumer at the heart of product design. It also shows the need to provide evidence that proves outcomes and safety. When one starts regulatory conversations with this mindset, experts agree that they have better regulatory success.

MedTech is uniquely positioned to navigate and turn perceived regulatory barriers into a competitive advantage. But to win in Digital Health, companies need to become more comfortable working within current environments. They must feel confident even where there may not be an established regulatory pathway. Furthermore, they must also collaborate with regulatory bodies to develop new guidance in parallel.

Key takeaways:

(1) Digital Health sits at the convergence of medicine and technology. It's governed by a number of different regulatory and legal frameworks and working groups within governing bodies.

(2) MedTech executives ranked regulatory uncertainty as a medium to high barrier. They agreed that it has an impact on their Digital Health agenda.

(3) Digital health stakeholders must work in regulatory spaces they are less comfortable in—or in some cases, work with the regulatory body to develop new guidance.

Digital Health, affordability and the economics of healthcare

The five trends outlined in this paper show a clear case for the greater adoption of Digital Health. However, there are additional barriers and considerations. Across the spectrum, healthcare costs continue to rise.

Digital Health: affordability and the economics of healthcare

The Center for Medicare and Medicaid Service (CMS) projects that US National Health Expenditure (NHE) growth will outpace GDP growth. It also projects that the share of NHE will increase from 18% of GDP in 2018 to 20% by 2028. In 2020, US NHE was almost at 20% primarily due to the COVID-19 response.

This rise is contributing to an affordability gap in developed markets. The gap is predicted to reach an estimated $300 billion by 2028.[32] In the US, the average premium for family coverage has increased 22% over the last five years and 55% over the last ten years. That's five times the rate of average wage growth experienced over the same period.[33]

In the EU5, the average premium for family coverage increased 38% percent between 2015 and 2019. This is roughly six times the rate of average wage growth experienced over the same period. In growth markets, health spending is projected to be highest in Brazil and China, both of which already spend the most on health.

Brazil's per capita healthcare expenditure is expected to grow from $681 in 2020 to $746 by 2030, while China's is expected to grow from $591 to $797 in the same period. A major part of this expenditure, around 33%, is out-of-pocket spending, and the trend is expected to remain the same in the upcoming years. In addition to China, India has a high share of out-of-pocket payments for health expenditure.

> It's clear that healthcare affordability is becoming untenable in most markets— and the reaction to the affordability barrier varies across age groups.

Millennials are more likely than other generations to take advantage of financial assistance. For example, rebates and non-profit services. They are also more likely to rely on digital technologies and digital therapeutics to manage their condition when they cannot afford healthcare. Gen-Xers and Baby Boomers, on the other hand, are more likely to explore alternatives that impact their treatment.
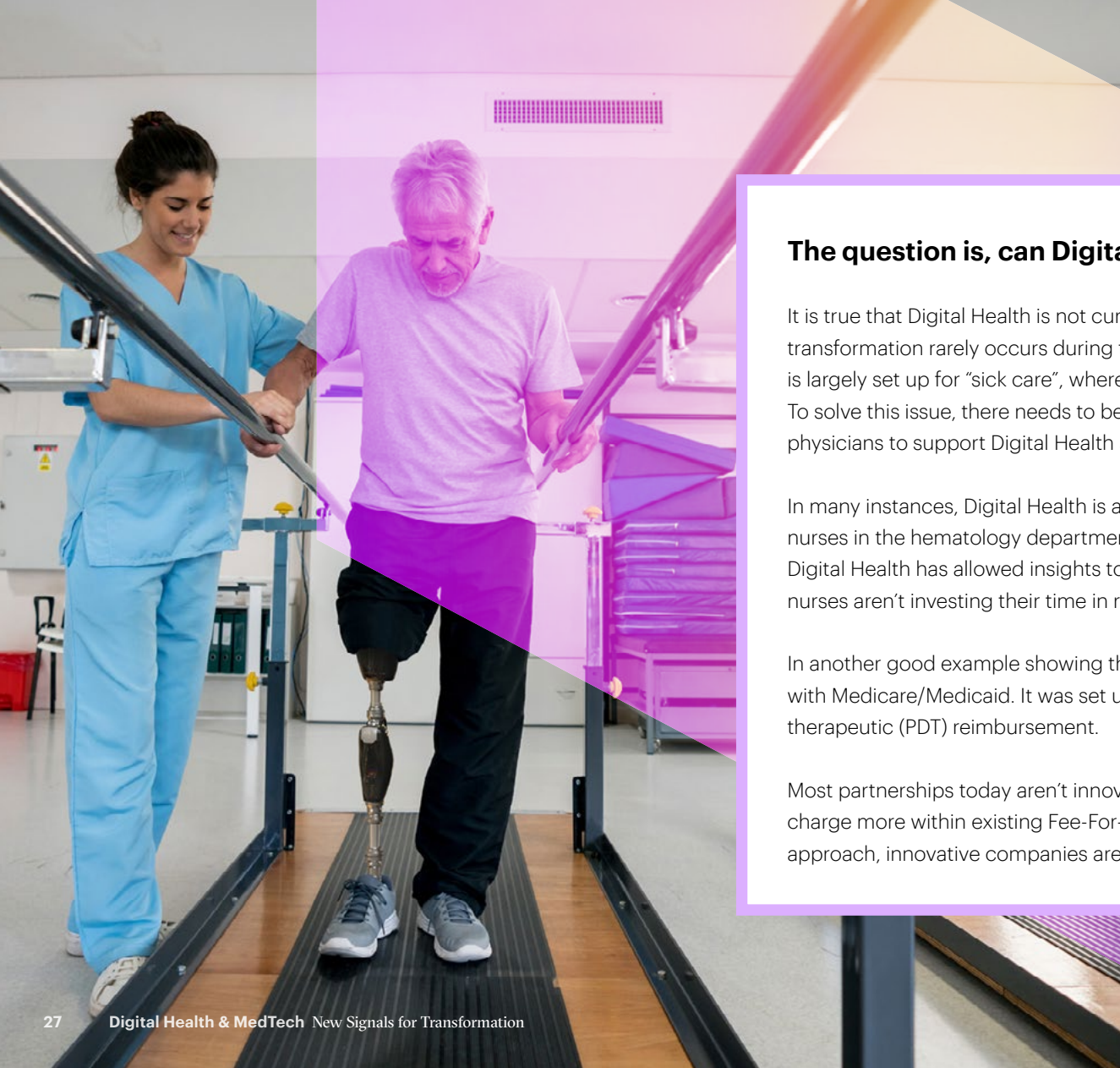
The question is, can Digital Health help solve this affordability challenge?

It is true that Digital Health is not currently a major profit driver in most cases. However, disruptive transformation rarely occurs during the beginning stages of adoption. The current health paradigm is largely set up for "sick care", where physicians are able to bill more if they treat sick patients. To solve this issue, there needs to be a shift in the reimbursement model. This will incentivize physicians to support Digital Health and preventative care.

In many instances, Digital Health is already helping save valuable time. In one health system, charge nurses in the hematology department spent the first hour of the day rescheduling everyone for the day. Digital Health has allowed insights to be aligned with pertinent rescheduling factors. Thanks to this, nurses aren't investing their time in rescheduling.

In another good example showing the value of Digital Health, Happify/Pear are involved in a program with Medicare/Medicaid. It was set up to look at policy changes and laws to support prescription digital therapeutic (PDT) reimbursement.

Most partnerships today aren't innovating the payment model. Instead, they're adding digital tools to charge more within existing Fee-For-Service (FFS) constructs with providers. By taking the alternate approach, innovative companies are helping reshape the cost pipeline.

Digital Health, MedTech and the Future of Healthcare

MedTech will lead the transformation of Digital Health. This is thanks to its unique understanding of therapeutics and patients. Growth is being driven by the increasing popularity of digital devices, many of which are already in the hands of consumers. However, the right digital foundation is needed to support these companies internally. Without it, digital insights will be difficult to leverage. These insights are critical to create a comprehensive Digital Health solution.

One C-Suite executive in our research summarized by saying, "(MedTechs) have to be leaders. Tech disrupters will eventually figure it out. If we do not lead in Digital Health, we are choosing to have our future market-share shrink. MedTech needs to build ecosystems to reach consumers everywhere, anywhere."

Medtech executives strongly believe the future winning strategy is to develop products and solutions to tackle the entire care pathway, with the Consumer Patient as a first priority. But at this stage, no single company alone has amassed all the capabilities required to serve the entire care pathway and drive the Digital Health ecosystem.

Therefore, traditional competitors must work together on pre-competitive initiatives. They must also collaborate with external partners. For example, with MedTech and other technology companies. This collaboration requires "open" standards and interoperability between the various partners. Critically, it needs internal regulatory, legal and privacy guidance with the appropriate internal teams to support them.

Healthcare is facing huge pressures around the world. Challenges range from affordability and the growing percentage of GDP spent on healthcare to shifting

Consumer Patient expectations. MedTech offers value through accessibility. It provides critical insights for both patients and physicians and and it improves costs. Companies are becoming more outcome-oriented through digital adoption. Therefore, reimbursement models also need to shift to incentivize HCPs to pursue more Digital Health solutions.

The key is understanding the barriers currently facing healthcare. This will enable companies to be better able to build strategies and create a more effective, affordable and innovative paradigm. The level of care will not only be sustainable but will continue to improve across the entire ecosystem.

The future of health is in the hands of MedTech.

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Appendix

We are taking a broad view of digital health, not as a vertical but rather as an evolving complement of digital technologies and data capabilities that are increasingly embedded across medical technology and healthcare. As a wide range of stakeholders, including healthcare providers, patients and consumers, adopt and integrate digital heath technologies, the net effect is increasingly efficient delivery of higher quality patient care and improved patient outcomes.

The digital revolution encompasses:
- **Data-generating and communications technologies that:**
  - Diversify and improve data collection and communications platforms within and outside of traditional, intensive healthcare settings through telehealth, encounter-based technologies, wearables, ingestibles and implantables to;
  - Enable collection of novel, real-time, more frequent, and/or continuous information that;
  - Yields new scientific insights into health and disease states (population and individual), enables remote or on-site monitoring and intervention, and empowers consumers and patients.

- **Aggregation, analysis and use of data**
  to advance scientific understanding; inform healthcare decision making; support research and development; facilitate product approvals and regulatory compliance; administer and evaluate value-based care; improve delivery and quality of care, including patient experience and empower remote and/or automated interventions.

- **Data-driven technologies that:**
  - Inform and or augment human decision making, and;
  - Effect remote and/or automated interventions.

Source: AdvaMed's Center of Digital Health

Appendix

In the US Medical devices including SaMD are classified into one of three regulatory classes:

- **Class One:** simple, minimal-risk devices that requires the lowest level of regulatory control, e.g. Cranial Measurement Software; Cranial measurement software is intended to be used to calculate and display physical measurements of the head for interpretation by a qualified user in conjunction with other clinical methods.

- **Class Two:** these devices may involve small to moderate risks to the user and are subject to few regulatory approvals, e.g. Coronary Vascular Physiologic Simulation Software—software that aids in the identification of functionally significant cardiovascular disease.

- **Class Three:** mainly includes life-sustaining high-risk devices that could cause significant harm to patients in case of a malfunction, therefore requires highest level of regulatory approvals and clearances, e.g. Software Option For Anesthesia Gas Machine to Achieve and Maintain Targeted End Tidal Oxygen and Anesthetic Agents; the software feature is indicated for use with the anesthesia system to support clinicians in maintaining the targeted end tidal oxygen and end tidal anesthetic agent concentrations that the clinician sets during an anesthetic procedure, by making multiple, limited adjustments to the fresh gas composition and total flow.

In the US, the FDA released an AI/ML-based SaMD action plan in January 2021. It outlines a series of steps authorities will take to expand the regulatory oversight of AI/ML-based SaMD:

- FDA's expectations for submissions related to software modifications.
- Harmonization of Good Machine Learning Practices.
- Promoting user transparency and a patient-centered approach to regulation.
- Improving algorithms to address issues such as bias.
- Proactive response to safety and usability concerns for AI/ML.

EU Artificial Intelligence Regulation risk based approach:

- Unacceptable risk, where AI poses serious threat to life, is banned.
- High-risk in AI-defined settings, such as a system failure that would put individual rights and health of citizens at risk, will be subject to extensive technical, monitoring and compliance obligations.
- Low-risk such as AI chatbots will be subject to minimal obligations.

In China, NMPA defines AI/Machine Learning (ML) SaMD as software that uses AI to analyze medical data for medical purposes and is most likely regulated as a Class 3 medical device.

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