



Consumer mHealth: How MedTechs can stake a claim in a surging market

Between rising demand, breakthrough technologies, and a supportive regulatory environment, the future of medical technology (MedTech) looks highly encouraging. One bright spot is the mobile health (mHealth) market, where existing health care companies and new market entrants are ramping up and products are giving consumers the chance for more involvement in their care. This

could be both a warning sign and a compelling opportunity for established MedTech players (e.g., medical device companies). They will need to figure out how to capture and/or sustain market share as competition increases, especially as nontraditional competitors from other industries aggressively penetrate this market.

The mHealth market heats up and competition increases

mHealth is the utilization of mobile technologies (e.g., smartphones, sensors, networks, analytics tools) to provide health care–related solutions across the patient journey. mHealth solutions have touched off a wave of interest from MedTech companies, as well as payers, pharmaceutical companies, providers, and, most importantly, patients themselves as they seek greater control over their health data and wellness.

This results in MedTech companies facing potential new competition in the mHealth space, including three types of established companies and new entrants:

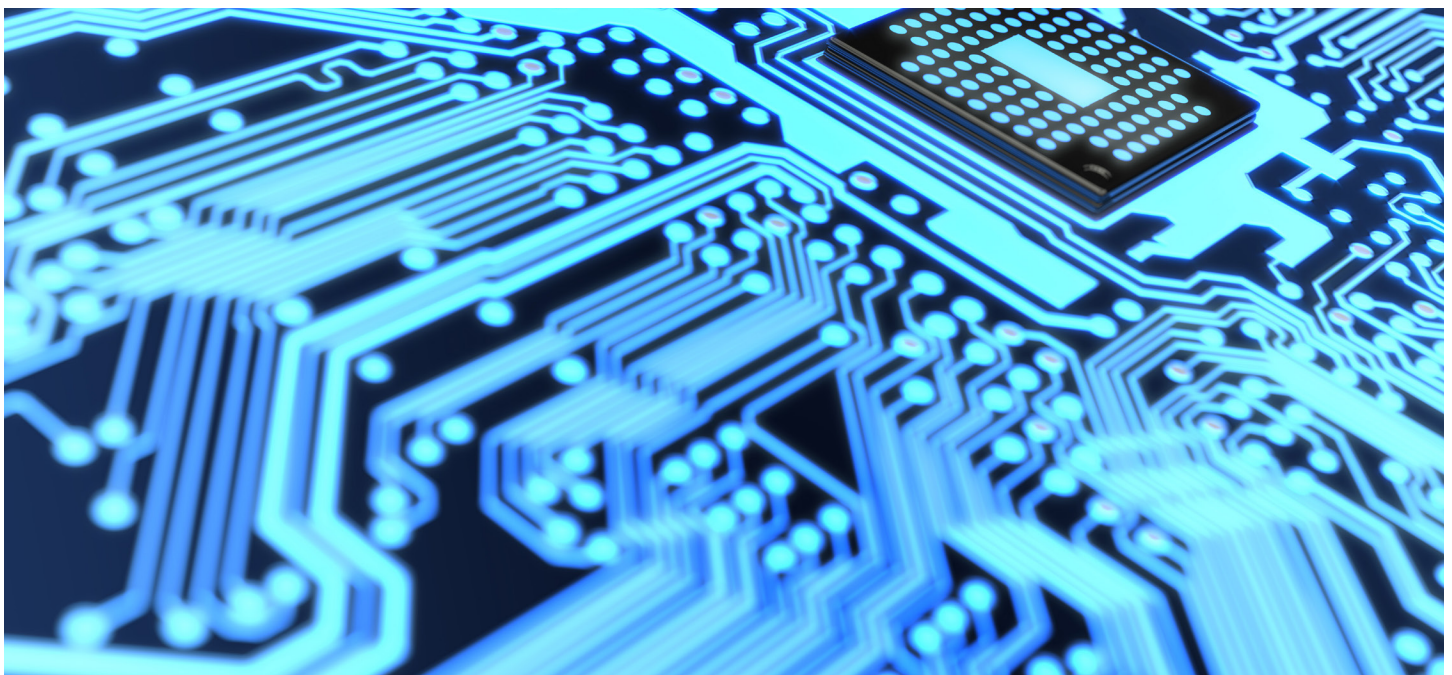
- **Consumer Technology:** Companies that are ready to capitalize on their software and hardware expertise in consumer technologies, strong hosting and analytics capabilities, and platform stickiness among consumers and businesses.
- **Business-to-Business Technology:** Companies that already offer many software, platform, and services solutions with potential application to the mHealth market, a wealth of data and the capability to analyze it, and, in some cases, established relationships with hospital administrators and physicians.
- **Pharmaceuticals:** Companies with therapeutic expertise, access to health care providers (HCPs) and patients, and years of experience with digital patient engagement.

These types of companies bring unique capabilities and strengths, and one company may fall into more than one type. Yet while these non-MedTech companies may be seen as competitors, they also represent potential opportunities for established MedTech companies to make ecosystem alliances that can accelerate efforts to gain traction and deliver value-added mHealth solutions across the patient journey and within traditional and new reimbursement structures.

Based on Deloitte's 2018 Consumer Health Survey, 60%–70% of patients with diabetes, pre-diabetes, heart disease, and lung or respiratory conditions indicated willingness to share mHealth data with their providers, emergency services, and family members to help manage their care.³



Apple Inc. recently released an update to its Apple Watch® Series 4 wrist-wearable device, which can take an electrocardiogram right from a user's wrist. Just weeks later, Sandoz and the digital therapeutics firm Pear launched reSET-O, a prescription mobile app to help wean patients off of opioid drugs. Both solutions are mHealth devices designed to help consumers in major disease categories to manage their health and reduce health care costs. They also aim to help HCPs increase patient engagement and improve patient outcomes. Both solutions had received clearance through the Food and Drug Administration (FDA) Pre-Cert Program, which promotes a more efficient framework for the review of digital health innovations.^{1,2}



mHealth success factors— MedTech executives weigh in

What factors might lead to success in the mHealth market? To better understand what makes an effective mHealth product, Deloitte conducted interviews with seven executives at companies ranging from MedTech startups to large medical device makers.

One thing the seven executives we interviewed have in common: All represent diabetes products. Diabetes is a chronic disease requiring active patient and care team engagement. It's also a widespread disease. More than 100 million US adults are now living with diabetes or prediabetes,⁴ and the economic cost of the disease in America was \$327 billion in 2017.⁵ The increasing disease burden has created an ongoing demand for and dynamic market around new and improved tools, considerable investment to address this demand, and a growing number of FDA clearances. It's also a disease area where mHealth companies have made significant headway and continue to explore possibilities for innovation.

During our conversations, we asked the executives about the challenges they face in mHealth and their views on key factors to succeed in this marketplace. We also discussed their views on key success factors, including smart insulin delivery devices, continuous glucose monitors (CGMs), and software applications, in the context of the diabetes life cycle and the need to support various applications, such as diagnostics, drug delivery, and tracking. Despite their different strengths, mHealth vendors identified a common set of needs. How effectively they meet these needs can determine their success in this nascent market.

Patients and caregivers are a group that includes patients managing their own chronic conditions and caregivers, especially those of children or elderly patients, who are co-managing the patients' condition.

Given the frequent communication among patients, caregivers, and HCPs, these stakeholders expect an intuitive, personalized user experience that enables data sharing. Patients and caregivers want to see specific data points, complete with actionable insights, to help know when to act on the data and actively manage their condition, particularly in type 1 diabetes. At the same time, they want a device that integrates easily with their lifestyle, providing data and insights only when necessary, so they are not reminded unnecessarily of their condition.

What this means is that even though this group is still a relatively small subset of mHealth early adopters, MedTech companies will need to develop consumer-centric solutions and consumer-targeted marketing strategies. They will also need to identify the most meaningful data, insights, and workflows to help HCPs (including doctors, nurses, and educators) and caregivers manage the patients' condition and encourage behavior change, since successful mHealth products drive behavioral changes that result in improved health. If the product is not reimbursable from a health care insurance perspective, innovative business and pricing models will need to be considered to encourage adoption.

“Patients don't want to be ‘engaged’ and driven to the app multiple times a day unless it is needed; too much engagement is a bad thing.”

– Former CEO of Diabetes Software Company

HCPs, including care teams, are key mHealth decision makers and some are early adopters of mHealth solutions. In the case of type 1 diabetes, HCPs are increasingly motivated by the potential of solutions to reliably improve patient outcomes. At the same time, some physicians are pushing back on the volume of data mHealth solutions can produce. They find it difficult to glean insights from the data in the short time they have face-to-face with each patient, so it can become more of a liability than a benefit. This is exacerbated when the solution doesn't integrate with the HCP's EHR and workflow systems and therefore requires extra time and effort after the patient visit. Also, HCPs may shy away from solutions having insufficient clinical study data, questioning the solution's efficacy.

Another interesting development is the change in roles of care teams, especially nurse practitioners and health coaches who are tasked with helping patients manage their conditions in between physician visits. As HCPs are increasingly reimbursed for their time providing support to patients and caregivers in this way, especially using telemedicine, their use of mHealth solutions is increasing in proportion to the number of patients and caregivers relying on the devices.

These factors have several important implications for MedTech companies. First, companies need to broaden their aperture beyond physicians when developing mHealth solutions and consider the role and needs of care teams and, as mentioned previously, caregivers. They should also talk extensively to HCPs before clinical studies and trials to understand what's important to

them and build those considerations into the studies. Finally, coming out of clinical studies and going into product launch, MedTech companies will want to develop and communicate a clear value proposition for all of the stakeholders, from physicians and care teams to patients and caregivers. Especially if there is a concern that physicians may see a device as a potential disruption to their practice, it will be important to communicate how the solution fits into the practice workflow and focus on both the medical outcomes and economic value in terms of time and cost savings.

Payers include both employers and third-party payers, which may have very different perspectives on whether an mHealth solution should be reimbursable. The decision may hinge not only on an understanding of patient risks and adherence but also how the mHealth solution improves member health and costs. The equation may be different for payers that typically manage members for a shorter time versus those, such as employers, that may manage their members for many years.

This means MedTech companies must have a good understanding of what data to collect that can produce insights that are meaningful to payers, especially those more heavily driven by return on investment. Regulatory acumen is important as well, so that data collection and reimbursement models remain in compliance. And, consideration should be given to innovative business and pricing models to incentivize payers to adopt a solution.

"[Providers] want something that will lead to better adherence in their patients and improve outcomes."

- VP Sales and Marketing of Diabetes Company

"If a tool helps a patient better manage their disease, then their health outcomes will be better, and payers will be more willing to cover the tool."

- General Manager of Diabetes at Life Sciences Company

Key mHealth capabilities

MedTech companies should focus on five specific capabilities that will translate into key success factors in the consumer mHealth market. It's important to note that potential competitors from the technology and pharmaceutical industries may already have some or all of these capabilities (Table 1). The first two capabilities focus on consumers, while the others center around value proposition, internal culture, and an ability to navigate the regulatory environment.

End-to-end product and service development. Companies with this capability apply user interface (UI) and user experience (UX) design principles early in their product development to make their products easy to work with, a factor particularly important to patients and caregivers, as noted above. As appropriate, they take into account the needs and end-to-end workflows of key constituents such as HCPs, health systems, device manufacturers, pharmaceutical firms, payers, and employers. They also design the products with easy onboarding and ongoing engagement in mind.

Beneath this capability lies an understanding of the kind of data that drives value and informs effective product design. This includes knowing what data the organization can access within privacy restrictions and permissions, ability to link different data sets, and the care gaps that data can fill. It also involves the technical know-how to develop algorithms that can help providers make decisions and patients gain personalized, actionable insights that drive improved outcomes and lower costs. Finally, this capability depends on Agile Software Development processes to rapidly prototype and pilot solutions, evolving the ones that work via cross-team collaboration.

Consumer (patient) marketing, onboarding, and engagement.

Consumer mHealth marketing begins with comprehensive, data-driven segmentation based on actionable customer variables and targeted behavioral objectives. The next step is to develop a value proposition and targeted messaging for each segment to address unmet needs and highlight the solution's emotional and clinical value. Part of this involves distributing direct to consumer (DTC) content across multiple channels, tailored to the target audience's preferences and fine-tuned via social listening and other real-time data gathering.

Companies that are strong in this capability also provide education and sustained support for patient onboarding and ongoing engagement, capabilities that are especially important for patients and caregivers themselves, as well as providers looking to maximize practice efficiency. This engagement model is supplemented with active data monitoring and gathering

of caregivers, care teams, and others to provide patients with the support they need. Leading companies perform real-time analysis within apps and devices as a critical means to understand when patients are and are not engaging, which allows solutions to be optimized to drive effective levels of engagement.

Economic value story. It's important to highlight not just a solution's clinical efficacy but also its economic and customer impact, a capability that's important to providers and payers alike. Real-world evidence, health economic and outcomes research (HEOR) models, and value-in-use data all help to tell a persuasive story. A value proposition that takes on customer concerns about economics, product life cycle, and competing alternatives can also help tell a persuasive story.

Table 1: Types of companies that are particularly effective with each capability

Capability	Types of companies that do this well
End-to-end product and service development	<ul style="list-style-type: none"> • Technology companies (which may already have integrated data sets on customers) • Digital health startups • Software companies
Consumer (patient) marketing, onboarding, and engagement	<ul style="list-style-type: none"> • Consumer wellness technology companies • Pharmaceutical companies
Economic value story	<ul style="list-style-type: none"> • Pharmaceutical companies (for economic value) • Technology companies (for business models, especially targeting patients) • MedTech (for HCP business models)
mHealth alignment and culture	<ul style="list-style-type: none"> • Digital health startups
Regulatory affairs and quality	<ul style="list-style-type: none"> • Digital health startups

Source: internal Deloitte analysis.

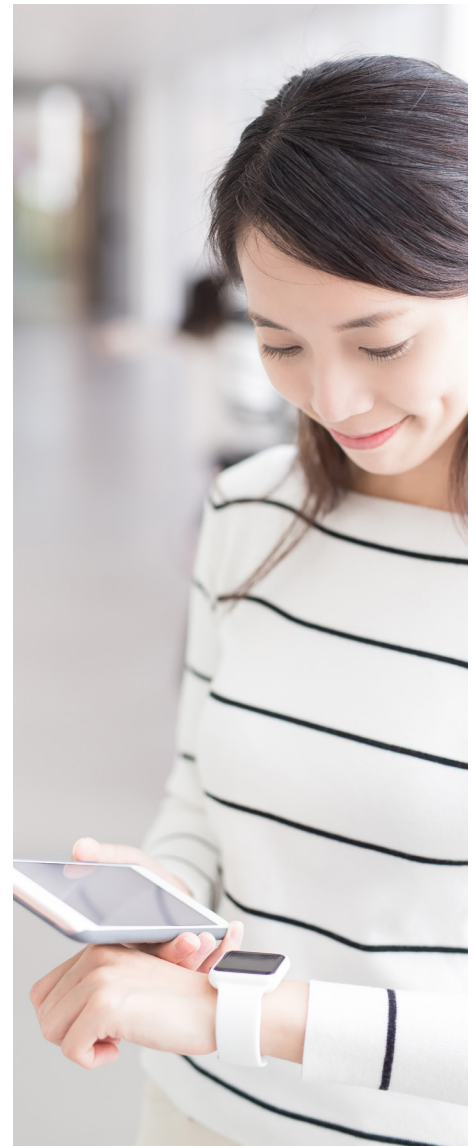
To these aims, a range of innovative business models may be up for consideration—including financial-based schemes (e.g., cost sharing), outcomes-based schemes (e.g., risk sharing or value-based), and software models (e.g., subscriptions based on patient usage instead of per-member/per-month pricing). Each of these business models requires additional capabilities, including people, processes, and technologies that can be critical factors in a successful launch. They may also necessitate a shift in mindset, such as focusing more on long-term profitability or offering the device at no cost but charging for the software.

mHealth alignment and culture. This capability depends on organizational buy-in. Business units and functions are motivated to collaborate around mHealth with clearly delineated roles, responsibilities, and decision rights. Newer initiatives have adequate funding, and mHealth capabilities are readily accessible.

Overarching everything is an organizational culture of continuous improvement, rapid iteration, and innovation. Some organizations create a separate “innovation accelerator” to encourage this kind of culture. Others create boundaries for the software teams working on software as a medical device (SaMD) solutions to allow them to have separate or modified quality management systems.

Regulatory affairs and quality. With this capability, companies can shape policy by actively engaging the FDA, advocacy groups, and other regulatory bodies. These companies understand policies and products to the extent that they can file for clearance. They stay abreast of regulatory changes and proactively consider ways to address them (e.g., the new FDA precertification process for SaMD). They also have an mHealth-oriented quality management system (QMS) that aligns with the risk level of the mHealth solution, which might be different than that of the organization's core device. This may allow for modifications to the QMS for the mHealth and/or SaMD solution.

These capabilities will only grow more important as: (a) consumers become more proactive about their overall wellness and take a more proactive role in their health management; and, (b) payers see an increasing volume of evidence that mHealth can drive better outcomes at lower costs. In this environment, companies taking mHealth products to market will need a consistent and effective customer focus that includes all stakeholders.



Closing the capabilities gap

MedTech companies have three basic ways to develop a leading capability:

1. Build it in-house
2. Build it in partnership with another company (including nontraditional players)
3. Acquire it from another company (or acquire the company itself)

Since the choice of which approach to take may differ by therapeutic area or a company's specific technology, and it may depend on the level of difficulty, the questions in Table 2 are intended to help provide clarity. If the answer to any of the questions in Table 2 is "yes," companies might consider developing the capability in-house. Otherwise, working with a partner or acquiring the capability inorganically may be an appropriate route.

Table 2: Examples of closing capabilities gaps via partnership or acquisition

Capability	Selected questions	If answer is "no," consider . . .
End-to-end product and service development	Can existing employees easily acquire these skills and develop an agile, iterative product development process?	Hiring additional personnel and/or partnering with external resources
	Does the company have patents for innovative biomarkers or medical devices that can be repurposed for mHealth?	Acquiring or partnering with appropriate external entities
Consumer (patient) marketing, onboarding, and engagement	Would target customer/patient segments be receptive to the company's brand?	Acquiring an mHealth company with a strong brand and large user base, which could be leveraged for future offerings
	Can existing sales, marketing, deployment, and capabilities support a direct-to-consumer strategy?	Partnering with companies to gain access to their expertise and potentially their customer base
Economic value story	Does the company already have innovative pricing models and/or partnerships with viable customers for mHealth?	Partnering with existing customers or partners to develop innovative pricing models that address value-based care or reimbursement
mHealth alignment and culture*	Does leadership believe enough of a culture of innovation and entrepreneurship exists, or can it be created?	Building an internal, autonomous mHealth business unit with different governance and funding structures, which will function as an agile, internal startup
		Partnering with outside company to develop this capability
Regulatory affairs and QMS*	Do governance structures allow for successful pilots to be adequately funded and scaled?	Building relationships with regulators and leveraging credibility to influence their stance toward mHealth-friendly policies, as well as leveraging outside resources

* Generally, this is a capability that companies want to keep in-house.

The bottom line—inaction isn't a choice for MedTechs

Whatever approach they take, MedTech companies that want to be serious contenders in the mHealth space will need to understand the market landscape, and their competitive advantage.

One option not on the table? Doing nothing. MedTech companies have built their success on a foundation of clinical research and development. But that foundation isn't enough in a quickly emerging mHealth market where competitors have an edge with focused initiatives, rapid development cycles, and consumer-oriented software and solutions. Make no mistake—the race is on, and if MedTech is to win, the time to start building these capabilities is now.



Medtronic Partners to build mHealth capabilities

The transition to value-based care is driving better outcomes and lower costs among key players in mHealth technology. Chairman and Chief Executive Omar Ishrak often describes Medtronic as being focused on creating a system of value-based health care in which companies drive revenue based on outcomes rather than products, diagnostic processes, or treatment methods.⁶ In 2016, Medtronic gained an advantaged formulary position with UnitedHealthcare—a first in the diabetes device arena.⁷ The company followed up in 2017 by carrying out a similar feat with Aetna. How? By using data from its connected mHealth solutions (e.g., Minimed[®] 670G system) and the solutions themselves to improve clinical outcomes and lower total cost of care.⁸

Capabilities maturity scorecard

Use this scorecard to determine where each capability stands on the path to maturity.

Capability	Trailing	Table stakes	Leading
End-to-end product and service development	<ul style="list-style-type: none"> Focuses unmet needs research on HCPs; develops products for target HCPs Shows gathered data without significant analysis Development timeline and method remains unchanged from traditional medical devices 	<ul style="list-style-type: none"> Develops products based on patient, HCP, and other stakeholder needs, but still using HCP-focused design Understands data important to target customers Practices agile development via prototype and pilot Conducts user research for initial product design 	<ul style="list-style-type: none"> Develops product UI/UX intuitive for patients, HCPs, and other stakeholders Leverages customer data in product design; understands data important to customers; and collects real-world data during and after pilots to facilitate data-driven road; if applicable, accelerates development process Incorporates customer feedback processes into R&D
Consumer (patient) marketing, onboarding, and engagement	<ul style="list-style-type: none"> Targets all patients in specific indication Messaging addresses unmet needs Content is generic and distributed across a few channels 	<ul style="list-style-type: none"> Targets specific segments in indication Messaging addresses unmet needs and emotional/clinical value Content is customized and distributed across a few channels based on segment Actively engages patient in onboarding and adherence 	<ul style="list-style-type: none"> Targets specific segments in indication by actionable and meaningful customer variables/target behavior Messaging addresses unmet needs and values Content is customized and distributed across multiple channels based on segment Actively engages patient and care team or others to encourage onboarding, adherence, and ongoing engagement
Economic value story	<ul style="list-style-type: none"> Value proposition focuses on unmet clinical efficacy Uses traditional pricing and contracting models 	<ul style="list-style-type: none"> Value proposition highlights clinical efficacy and economic/customer impact Weights traditional business models, taking all stakeholders into account 	<ul style="list-style-type: none"> Value proposition highlights clinical efficacy and economic/customer impact, supported by robust data (e.g., RWE, HEOR, value-in-use) Weights a range of business models, taking all stakeholders into account
mHealth alignment and culture	<ul style="list-style-type: none"> Leadership has declared their endorsement mHealth has little investment or alignment Efforts to change for innovation are hesitant 	<ul style="list-style-type: none"> Leadership has endorsed and aligned with mHealth mHealth has some investment, but a short-term ROI focus The mHealth department has an innovation culture 	<ul style="list-style-type: none"> Leadership has strong alignment and investment in mHealth The mHealth department has a strong innovation culture and short- and longer-term ROI focus Product groups bring in mHealth expertise as appropriate
Regulatory affairs and QMS	<ul style="list-style-type: none"> Develops a strategy to address regulatory changes once the changes are issued Existing regulatory professionals (without mHealth experience) try to influence regulations 	<ul style="list-style-type: none"> Stays abreast of regulatory changes and proactively thinks through a strategy to address them 	<ul style="list-style-type: none"> Actively engages with the FDA, advocacy groups, and other regulatory bodies and outside experts to drive mHealth policy and improve QMS processes Stays abreast of regulatory changes and proactively thinks through a strategy to address them

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Endnotes

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We wish to thank **Jamie Baron, Srihita Bongu, Rick Altinger** and others who contributed their ideas and insights to this project.



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