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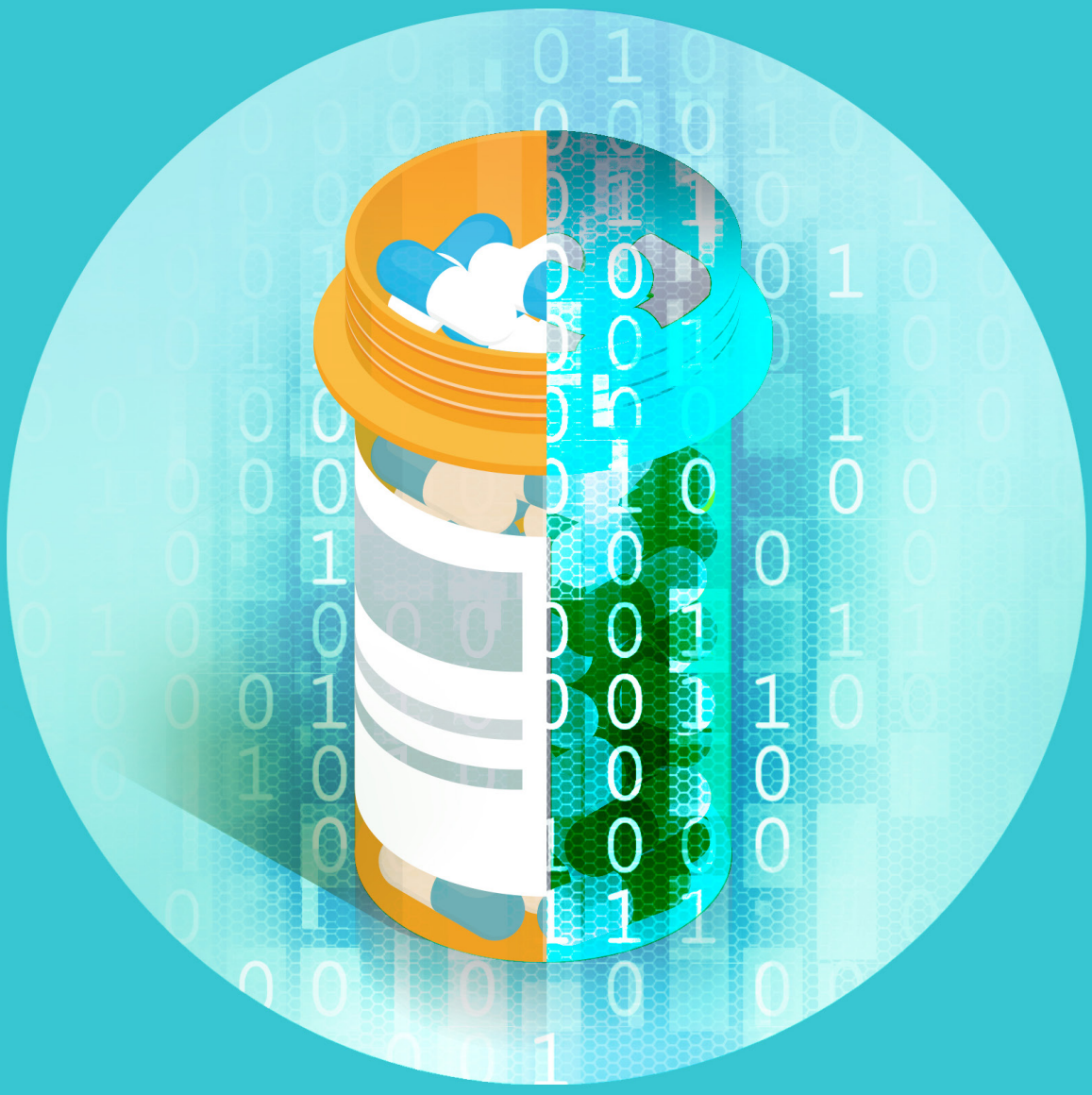
A report from the
Deloitte Center for Health Solutions
and the Digital Medicine Society



Personalized therapies in the Future of Health

Winning with digital medicine products

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Executive summary

THE LAST FEW years have witnessed a proliferation of digital medicine products, including *digital therapeutics* (i.e., regulated products that employ software to deliver evidence-based therapeutic interventions) and *digital companions* (i.e., products that provide additional services and insights for patients to improve their experience, knowledge, and outcomes of their existing drug therapy). The potential for their use in conjunction with or as an alternative to drug therapies has sparked interest among many companies, even outside of traditional health care and life sciences, including large technology players and digital health startups.

In our Future of Health™ vision, we expect some diseases will be prevented, managed, or cured with nonpharmacological interventions such as digital therapeutics. These interventions could reshape the health care industry, shifting the focus toward prevention and well-being, moving care outside of health care facilities, and putting consumers at the center of their own care. Even today, digital medicine products are beginning to transform health research and care models, and the COVID-19 pandemic has accelerated this transformation.

Our view is that life science companies that reimagine their business models and put the consumer-patient at the center, will be most likely to succeed in this future paradigm. Incumbents' clinical and regulatory expertise puts them in a strong position to commercialize digital medicine products in a highly regulated environment and win over digital innovators and other entrants by doing this at scale. This will require new capabilities.

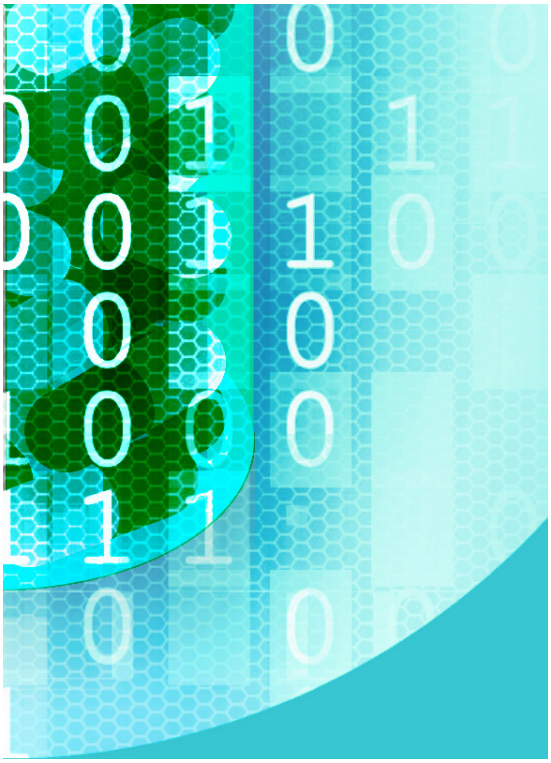
In our Future of Health™ vision, we expect some diseases will be prevented, managed, or cured with nonpharmacological interventions such as digital therapeutics.

To what extent are biopharma companies effectively moving and investing to capitalize on the digital medicine product opportunity today? We interviewed 41 executives from life sciences, technology, payer, and provider organizations to better understand the current state of digital medicine products. We found that:

Biopharma companies are experimenting with digital medicine products

- Digital medicine products offer the opportunity to become more patient-centric, influence patient adherence and outcomes, better understand the patient experience of disease, and generate real-world data that is relevant to customers.

- However, biopharma companies are still figuring out how to tap this opportunity at scale. Many have experimented with *digital companions*, but few are developing *digital therapeutics*.



Business models are evolving as reimbursement remains a challenge

- Market access pathways for digital medicine products remain ill-defined.
- Pharma companies expect most *digital companions* to enhance revenue for core products rather than create a separate revenue stream; therefore, companions are typically offered for free or built into the pricing of the pharmaceuticals they support.
- Developers of *digital therapeutics*—mostly small technology companies with a specific clinical focus—are testing multiple commercialization models, (including direct to consumer, direct to provider, and coverage under medical benefit). But there is no clarity on the winning model or models that will be required for sustained commercial viability.

Operating models to support digital medicine products are in early days

- Today, most biopharma companies partner with large technology companies or small digital therapeutic developers; few have yet decided to build digital medicine products in-house.
- Most companies have or are in the process of standing up a centralized digital function, which acts as an adviser to product teams to identify unmet needs and select technology partners. Some are creating similar leadership roles in R&D to align digital medicine product strategy to the therapeutic strategy earlier in the process.

Digital medicine products call for new approaches and capabilities while leveraging core competencies that can provide strategic advantage. Based on our research, we recommend biopharma companies:

1. **Articulate a clear vision** of how their digital medicine product strategy will create value within the broader digital health ecosystem in conjunction with their therapeutic strategy, recognizing that each therapeutic area (TA) is likely to have distinct differences based on the etiology of the disease.
2. **Leverage their strengths and experience** of understanding the patient journey, the clinical evidence generation process, and the regulatory pathways to bring products to market.

3. **Define and implement an operating model and decide whether to build product development capabilities in-house or partner/outsource.** If developing digital medicine products is core to the strategy, companies will need to cultivate new expertise and talent pools with requisite skills in software design, agile development, medical device regulation, software quality management systems, and digital product management.

4. **Reinvent the development process.** Building digital medicine products requires rethinking the traditional development processes. The iterative nature of building software calls for tighter coordination between commercial, medical, regulatory, and development teams.

5. **Expand the traditional business models.** The traditional commercialization and acquisition playbook may not be enough. Pharma companies may need to build relationship with new stakeholders or change relationships with existing ones; and business development opportunities should take into account digital medicine products.

The age of digital medicine products is here, and life science companies that can identify a clear place for themselves within this burgeoning ecosystem will likely see a competitive advantage.

Introduction

MULTIPLE STAKEHOLDERS INVOLVED in digital health (including the Digital Therapeutics Alliance [DTA] and Digital Medicine Society [DiMe]) have collaborated to define *digital health* as technologies, platforms, and systems (such as health IT systems, mobile apps, telehealth platforms, and wearables and sensors) that engage patients for lifestyle, wellness, and health-related services.[1] Such products support prevention, diagnosis, treatment, and management of health and disease. *Digital medicine* products are a subset of digital health and include evidence-based software and hardware products that measure and/or intervene in the service of human health.[2] A growing number of startups and technology companies are introducing innovative digital medicine products to enable patients to take greater control of their health.[3] In this paper, we focus on two categories of these products: 1) *digital companions* to drugs and 2) *digital therapeutics* (figure 1 has definitions and examples).

In our Future of Health vision, we expect health care will shift to prevention and wellbeing and become centered around consumers' needs. Consumers are becoming increasingly active participants in their own health and care, and this will accelerate as new digital health tools and platforms become available and provide more value. With full visibility into and control over their health information coupled with AI, consumers should be able to make health-related decisions and perform many activities that today require a clinician's involvement. Digital medicine products will likely be used at scale for prevention, proactive care, and as stand-alone treatments. For instance, they could make existing treatments more effective, reduce the need for medications by supporting sustained behavior change, or in some cases even become a viable alternative to traditional pharmacologic treatments.[4]

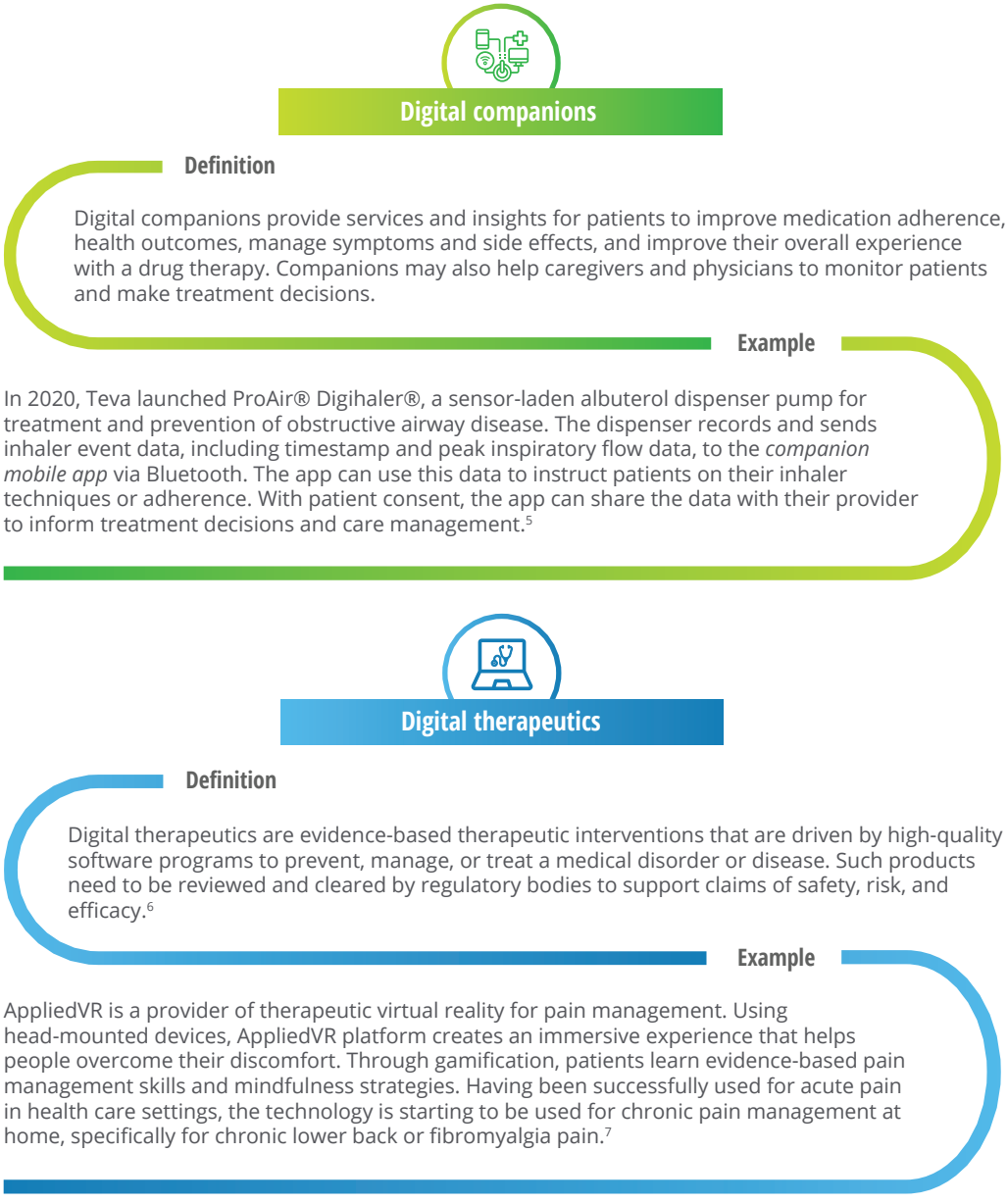
Consumers are becoming increasingly active participants in their own health and care, and this will accelerate as new digital health tools and platforms become available and provide more value.

ABOUT THIS STUDY

The Deloitte Center for Health Solutions collaborated with the Digital Medicine Society (DiMe) to study the current trends around development and commercialization of digital medicine products. Between September and November 2020, we conducted 35 interviews with 41 digital health experts to understand leading practices, needed capabilities, reimbursement landscape, and challenges. Interviewed executives included heads of digital health functions, medical directors, and strategy officers from life sciences companies, providers, and payers, and CEOs of tech companies. The goal was to develop a comprehensive look at what has worked well, lessons learned, and where the market is heading.

FIGURE 1

Digital companions vs. digital therapeutics: Definitions and examples



Source: Deloitte analysis.

We are beginning to see elements of Deloitte's Future of Health vision take shape today. The Deloitte 2020 Survey of US Health Care Consumers shows use of technology for health and fitness has increased rapidly since 2013, and the COVID-19 pandemic has accelerated many of these trends.[8] The percentage of consumers using virtual visits grew from 15% in 2019 to 28% in April 2020.[9] Going forward, the optimal level of virtual visits is expected to be similar to the peak witnessed during the pandemic, according to the Deloitte 2020 Survey of Health System Clinical Leaders. For primary care and chronic care management, this means between 30% and 34% of the visits should be

virtual, up from only 5%–6% prepandemic. Regulators, too, recognize the importance of digital health, and during the public health emergency period, a number of regulatory flexibilities expanded access to digital health products and virtual health services in the United States. (See sidebar "Changing regulations aim to expand access to digital health products.")

Although thus far innovations in digital health, including digital medicine products, have come from the tech sector[10] (figure 2), we believe biopharma companies should capitalize on these opportunities: Their scale and their clinical and regulatory expertise put them in a strong position to commercialize digital medicine products in a highly regulated space and win over digital innovators and other entrants. To accomplish this, however, they should invest in new capabilities in software product management and engineering talent and make cultural shifts toward more agile ways of executing development.

CHANGING REGULATIONS AIM TO EXPAND ACCESS TO DIGITAL HEALTH PRODUCTS

The 21st Century Cures Act of 2016 laid the groundwork for new regulatory frameworks for digital health.

- The Cures Act established the Food and Drug Administration (FDA) Breakthrough Devices Program used by some digital therapeutic innovators to bring their products to market. Additionally, the Cures Act excludes health and wellness digital products (such as mobile apps and other tools that encourage a healthy lifestyle) from FDA oversight.[11]
- The Digital Health Innovation Action Plan announced in 2017 clarified the medical software provisions of the Cures Act, launched a pilot precertification program to develop a new approach to digital health technology oversight, and set out plans to build a cadre of digital health experts.[12] The Digital Health Software Precertification (Pre-Cert) Program recognizes that traditional medical device pathways, such as 510(k) and De Novo, are not optimal for digital medicine products or software as a medical device (SaMD), and may limit the ability to bring new products to market or to make changes to existing ones. The program aims to develop an innovative approach for accelerated review and oversight of digital health products by "looking first at the digital health technology developer, not the product." This involves precertifying companies that demonstrate a commitment to a culture of quality and organizational excellence and monitoring the real-world performance of their products. Precertified companies will be able to market their lower-risk products with only a streamlined premarket review or bypass the premarket review altogether.[13] For more, see Reimagining Digital Health Regulation.
- In 2019, the FDA began a pilot with a few organizations to evaluate the feasibility of the Pre-Cert model. The goal is to determine if this model can provide the same quality of information on safety and effectiveness as traditional approaches. FDA continues to test and iterate the model.
- In 2020, the agency set up the Digital Health Center of Excellence to provide centralized expertise and serve as a resource for digital health innovators, the public, and FDA staff.[14]
- In January 2021, the Digital Health Center of Excellence released the Artificial Intelligence/Machine Learning Action Plan which further describes FDA's proposed regulatory framework around AI/ML-based digital health technology to inform the industry on FDA's thinking on the subject.[15]

COVID-19 CREATES TAIL WINDS FOR DIGITAL HEALTH

During the public health emergency period, a number of regulatory flexibilities expanded access to digital health products and virtual health services in the United States.

FDA expands access to digital health products for mental health

For the duration of the pandemic, the FDA has waived several requirements for digital health products for mental health and psychiatric disorders. These include 510(k) submission, registration and listing requirements, and unique device identification requirements.[16]

CMS waives many virtual health restrictions

A few companies took advantage of this opportunity releasing their products on a limited basis prior to their final FDA approval. Akili Interactive Labs released EndeavorRx, a gamified digital therapeutic to improve attention in children with attention deficit hyperactivity disorder.[17] Orexeo, a Swiss pharmaceutical company, launched its digital therapeutic products Vorvida for problematic drinking and Deprexis for depression in the United States.[18]

To help Americans stay safe while getting access to health care, the US Centers for Medicare & Medicaid Services (CMS) and the Trump administration made many temporary changes to telehealth regulations, waiving certain restrictions and providing other flexibilities, such as:

- Removing requirements that a patient must be an established one to receive virtual health services and allowing payment for smart phone and audio-only phone calls
- Modifying and simplifying consent forms and allowing telehealth visits to take place in both the patient's and the clinician's home
- Encouraging states to use virtual health in Medicaid

While the flexibilities are tied to the pandemic and will likely be pulled back or modified when the public health emergency is declared over, many expect regulators to use the normal rule-making process to take into consideration what was learned during the emergency and what flexibilities should be adopted moving forward.

FIGURE 2

Companies active in the digital medicine product space

Organization type	Current focus and offerings	Key characteristics and capabilities
Digital therapeutic innovators (e.g., Pear Therapeutics, Happify Health, Voluntis)	◆ Have launched TA- and disease-specific digital therapeutics and companions ◆ Provide development platforms and services to pharma companies for digital medicine product development	◆ Tend to be small, niche players ◆ Deep clinical and technological expertise makes them adept at digitalizing clinical measurement, and gamification to promote behavioral change ◆ May not have end-to-end capabilities, particularly in commercialization ◆ Limited ability and resources to scale
Digital care specialists (e.g., Omada Health, Welldoc, Livongo)	◆ Focus on high-prevalence chronic conditions such as diabetes, CHF, and COPD ◆ Expansion into wellness and prevention ◆ While they have the capabilities to develop therapeutic care interventions and digital companions, they do not think of themselves as digital medicine product companies. ◆ Digital interventions are often supplemented with phone-based health coaching and disease management.	◆ Medium-size companies, with brand recognition and expertise in care management and population health ◆ Established relationships with commercial payers and providers; far less activity with government payers or life sciences ◆ Products already actively used and paid for by insurers and employers ◆ Access to large amounts of patient data and ability to generate health economic evidence
Consumer tech companies (e.g., Apple Inc., Google, Amazon)	◆ Have launched devices and wearables with the ability to capture biometric data and patient-reported outcomes ◆ Provide software development and consumer tech expertise to pharma companies ◆ View health care as an opportunity	◆ Large well-financed companies with appetite for acquisitions ◆ Expertise in consumer behavior, user experience, and big data and analytics ◆ Ability to connect health care data with data from other domains (financial, purchasing and consumption, geolocation, behavioral data, etc.) ◆ Building deep TA expertise to develop and commercialize prescription digital medicine products may be difficult.

Source: Deloitte analysis.

Research findings

THIS RESEARCH HAS many parallels to our first real world evidence benchmarking survey five years ago.[19] Biopharma companies understand the increasing importance and transformative disruption digital medicine products will bring to the industry. Most companies established small teams focused on the disruption. However, most efforts are relatively small in scale with heavy dependence on external collaborations vs. building in-house enterprise capability, and there is still uncertainty on how big to bet and how much capability to ultimately build in-house vs. outsource.

Biopharma companies are experimenting with digital medicine products

Interviewed executives expect the importance of digital medicine products to increase as a strategic priority, and spoke of growing investments in digital capabilities. As patients become more empowered to make their own therapy and treatment choices, the ability to directly engage with them will grow in importance. Digital medicine products present an opportunity to move beyond the pill, better understand patient needs and patient journey, and enhance patient experience and outcomes while on a therapy. Our interviewees highlighted some of the benefits of digital medicine products:

- Increasing adherence and persistence can improve patient outcomes and generate additional revenue from existing branded products.
- Better patient education about their disease and medication and improved management of co-morbidities and symptoms, such as anxiety and depression, can create a closer relationship with patients, improve their experience, and strengthen brand loyalty.
- Capturing patient-reported outcomes can improve understanding of the patient journey and disease progression, improve care coordination, and support pharmacovigilance. There are also opportunities to use this data for market access and regulatory purposes.

Recognizing these benefits, many biopharma companies have invested in digital companions (i.e., pairing digital tools with drugs). As they all pursue a similar approach, we expect that going forward, digital companions may not be a point of differentiation but table stakes in many disease areas.

"Our digital companion strategy is not just about the patient but the entire spectrum of needs: adherence, access, and affordability, and from health care professionals' perspective, diagnosis, treatment, identification and awareness of a disease, and helping to treat that disease. We are looking at this from all points of view for each of our customers."

— ***Senior VP of digital, mobile, and user experience, biopharma company.***

MEASURING RETURN ON INVESTMENT IN DIGITAL COMPANIONS

Executives we interviewed say it can be difficult to accurately estimate ROI from digital companions. Companies are experimenting with multiple metrics and approaches for assessment. A common approach is to analyze the companion's ability to improve adherence to treatment protocol and support patient engagement. Metrics include usage statistics (number of downloads, ongoing usage, and frequency), adherence to drug therapy, staying on therapy, and patients' feedback.

One interviewed company makes its investments in digital companions contingent on achieving predetermined milestones. Once a minimum viable product is built, the company conducts a proof of concept to understand its uptake and benefits to patients. This involves a variety of qualitative (observation and interviews with patients) and quantitative (usage metrics, uptake at the time of promotional activity) assessments. Based on the data, a decision is made on whether to invest in a full-scale launch or to tweak the companion and reassess its performance: *"If we go through a number of release cycles and we're not making a substantive improvement on the asset, we pull it out of the marketplace."*

Business models are evolving

The business case for digital therapeutics is less clear than for companions, at least for now: The economic benefits, the opportunity cost, and reimbursement pathways are unclear. Only a few of the biopharma companies interviewed have invested in digital therapeutics, and even fewer have created structures to develop and commercialize such products in-house. Doing so would likely require new operating models across R&D and commercial.

Not all TAs lend themselves to digital therapeutic or monitoring solutions with therapeutic features. Through our interviews, we have identified only a handful: behavioral health conditions, such as depression, anxiety, addictions, PTSD, and insomnia; movement disorders such as chronic stroke or Parkinson's disease; chronic and acute pain; and diabetes. For biopharma companies that don't already play in these TAs, investments in developing therapies—digital or conventional—for these conditions could siphon away resources from the core business. We also heard that the scientific process of discovery and regulatory pathways for digital therapeutics have more similarities to medical devices than to traditional pharmaceuticals.

Since digital companions are expected to enhance revenue from existing drugs rather than create a separate revenue stream, most biopharma companies intend to offer digital companions for free, with software development absorbed into the cost of the core product. Seeking regulatory review

"The revenues in the CNS space for depression and anxiety are modest compared to other TAs. Even if you consider MS, can a digital therapeutic take the place of an $80,000 drug? No, not at all. Other TAs, like diabetes or hypertension, are very low margin drug areas."

— ***Head, digital therapeutics company***

and approval is not typical, and many digital companions under development will be available without a prescription.[20] We have heard of digital companions being developed in several TAs: oncology, multiple sclerosis, hemophilia, diabetes, and respiratory conditions. However, questions remain about the ROI, especially in TAs with effective and inexpensive treatment options, such as diabetes or heart disease.

Reimbursement is a key challenge

From our interviews, digital medicine product developers are exploring the following reimbursement in the United States:

DIRECT-TO-CONSUMER

- Under the **direct-to-consumer** (DTC) approach, users pay subscription fees to access digital therapeutic applications. These models have had mixed success because consumers generally expect their health care costs to be covered by their insurance or employer, particularly for chronic conditions, and DTC marketing can be expensive.[21]

- For digital companions available without a prescription, DTC is expected to be the primary channel, mainly through pharma companies' customer support programs.

COMMERCIAL PAYERS: FULLY INSURED

- Coverage under the **pharmacy benefit** would be the most likely approach for prescription digital therapeutics; but so far, we have seen few examples. While an FDA approval could make the product eligible for formulary inclusion, payers will want evidence that a digital intervention lowers the cost of care.

- Digital therapeutics with a hardware component can be covered as durable medical equipment (DME) under the **medical benefit**. Stand-alone digital therapeutics (regulated as SaMD products) can pursue reimbursement in the same way as conventional medical devices, but we have seen little success to date.[22]

- Insurers indicated that in the future they may support an "**over-the-counter**" **approach** to digital companions, and possibly therapeutics, by directing members to information about the product but having the member pay for it. The mechanism to do so is not in place yet.

COMMERCIAL PAYERS: SELF-INSURED

- In this model, digital care specialists sell directly to a self-insured employer that offers the product to its employees, either through a care management program or as a wellness benefit. Pricing can be per user per month or in the form of licensing fees.

"Welldoc found that, as a prescription product, taking the payer route and the physician route was really tough. Now they have direct-to-employer business model where the employer pays for it and offers it to the patient (without a prescription)."

— ***Head, digital therapeutics company***

- Digital medicine products can be part of outcome-based contracts with payers, where the contract is tied to outcomes or reduction in overall cost of care, but this practice doesn't appear to be widespread. We have seen examples of cost sharing or pay-for-performance tied to user engagement, adherence, or patient-reported outcomes, and less commonly, to clinical measures or cost of care (mainly in diabetes).

DIRECT-TO-PROVIDER

- Several digital medicine innovators sell or license their products to health care providers, who in turn make them available to patients. This approach tends to work when:
  - Digital products are used in-clinic (like virtual reality)
  - There is a remote patient monitoring component that relays data back to the providers for use in clinical decision-making
  - A reduction in patient visits for monitoring, treatment, or diagnosis is offset by reimbursable activities (like remote patient monitoring) or happens in fixed budget scenarios (like bundling or capitation)
- For the most part, existing payment models for providers do not offer sufficient incentives to adopt digital medicine products or a new standard of care. Greater adoption of value-based payment models may change that if digital medicine products help providers reduce the cost of care or improve performance on quality measures used in the payment systems.

Traditional fee-for-service payment models (e.g., tying payments to claims for clinical activities like therapy or diagnostics, DME, or a national drug code) do not always work for digital therapeutics. Some digital therapeutics developers voiced criticisms that payers do not apply the same criteria to digital that they do to conventional therapeutics and refuse to pay even when there is a cost and/or quality benefit against the standard of care. And from payers we heard concerns that digital therapeutics can create new costs. For these reasons, many digital care specialists and some digital therapeutic innovators find direct-to-employer sales a more effective business model than working though health insurers or pharmacy benefit managers.

"Even when cognitive behavioral therapy (CBT) is covered under the medical benefit (as opposed to carve-out), we'd want evidence the digital app will be *replacing* in-person visits. But if it's used in conjunction or in addition to in-person CBT, then you are adding expense."

— ***Medical director, national health plan***

We have identified little activity with government payers in the United States. If digital health companies choose not to pursue reimbursement from government payers, it could potentially exacerbate the digital divide by excluding patient populations of lower income and with higher disease burden.

PAYERS PREPARE FOR DEMAND FOR DIGITAL MEDICINE PRODUCTS

Even though digital medicine products have not been a priority for payers, some are experimenting with new reimbursement models to support patient access to these products

Examples from the United States

- In 2020, CMS proposed a new coverage pathway, *Medicare Coverage of Innovative Technology* (MCIT), to provide national coverage for FDA-designated breakthrough devices for four years from launch. In the interim, device manufacturers can collect clinical and real-world evidence on the impact of their products on health outcomes.[23] One interviewed company took advantage of this pathway and is pursuing DME reimbursement for its product that comes with a sensor.
- A major PBM established a digital health formulary or a platform that enables plan sponsors to add digital health products to their standard benefits. Products on the platform are evaluated for clinical effectiveness, usability, and affordability. While not a formulary in its traditional sense, the platform promises to reduce the administrative burden for plan sponsors associated with contracting and managing multiple digital health vendors.[24]

Examples from Europe

- Germany launched a pilot that allows product developers to be reimbursed by payers in the first year, and this period is used to gather outcomes data. After the first year, based on data, companies can negotiate reimbursement with payers.[25]
- In France, a tech company and its pharma partner entered into a shared savings agreement with the national payer. Any cost savings above 15% are split between the payer and the tech-pharma partners.

Operating models to support digital medicine products are in early days

Our research has brought to light early operating models that companies are experimenting with. Most drug companies we interviewed are partnering with technology companies to build digital companions. A few are building and launching digital companions in-house.

Regardless of the buy or build approach, most companies have or are in the process of standing up a digital function that provides resources and expertise for digital product development.

"We are very much focused on the patient problem for digital innovation. It's about 'What is the patient challenge and where is the problem?' We then proceed to the market and figure out what is the right technology or innovations to help resolve this issue that we're seeing."

— ***Director, corporate strategy and innovation, biopharma company***

The digital function typically acts as an adviser and strategic partner to product teams to identify and articulate unmet patient needs and create digital solutions to support them. Digital solution teams often undertake desk or primary research and engage with brand and product development teams, patient groups, and key opinion leaders to identify the patient needs a digital solution should address. Some teams conduct ideation and cocreation sessions with patients and physicians to test initial concepts and prototypes. The digital team also identifies, vets, and matches external technology vendors with internal needs and technology requirements, even at companies that have in-sourced much of the work.

Organizations typically choose to house their digital resources in commercial or in R&D, or as an enterprise function under IT. While the primary benefit for concentrating digital capabilities within R&D is to digitize the clinical development process, it also makes it easier to consider digital companions earlier in the drug development cycle. Moreover, close coordination with R&D teams enables creation of digital companions that could be used across entire TAs and brands. On the other hand, positioning digital expertise within the commercial function supports deployment of digital companions for on-market products and enables closer coordination and access to marketing resources.

Our research suggests that funding sources for digital medicine product development differ across and even within organizations. Funding is a mix of a fixed amount from a central budget dedicated to digital staff and to cross-functional digital initiatives and variable project-specific funding from brand teams, R&D, or commercial functions. At several companies we interviewed, the funding and budgeting process was ill-defined, leading to an inability to commit to multiyear programs. Even if processes do exist, executives described difficulties. For instance, one executive said the annual budgeting cycle is not conducive to digital medicine products' fast product development cycles: It is difficult to access funding (e.g., mid-year) to begin product development as soon as a need is identified. As a potential solution, the company is contemplating funding digital companion projects through a corporate venture capital fund.

Our research suggests that funding sources for digital medicine product development differ across and even within organizations.

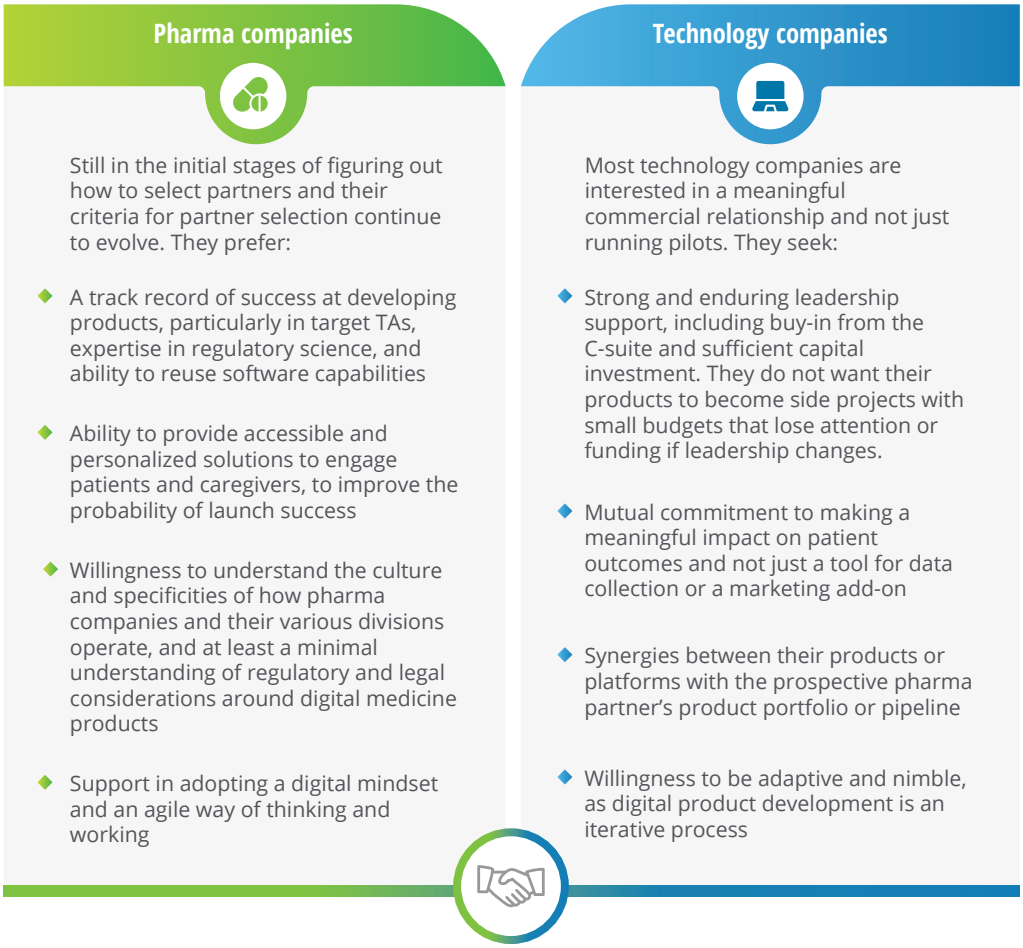
PARTNERING WITH TECHNOLOGY COMPANIES

Pharma companies are partnering with technology companies, consultancies, and digital health startups to access the expertise to build digital medicine products. Internal teams from biopharma companies (where the digital function exists) assess the tech landscape to identify potential partners that best suit their needs.

Partnerships can involve access to a propriety technology platform that is often TA-specific. For instance, BMS has partnered with Voluntis to use its Theraxium Oncology platform to build a digital companion for self-management of symptoms related to cancer therapy.[26] Sanofi partnered with an established mental health digital therapeutics firm, Happify Health, to build a digital therapeutic to help multiple sclerosis patients manage anxiety and depression.[27] Technology companies are likely to remain important partners for biopharma as a source of expertise and innovation in digital medicine products.

FIGURE 3

Key considerations for partnering



Source: Deloitte analysis.

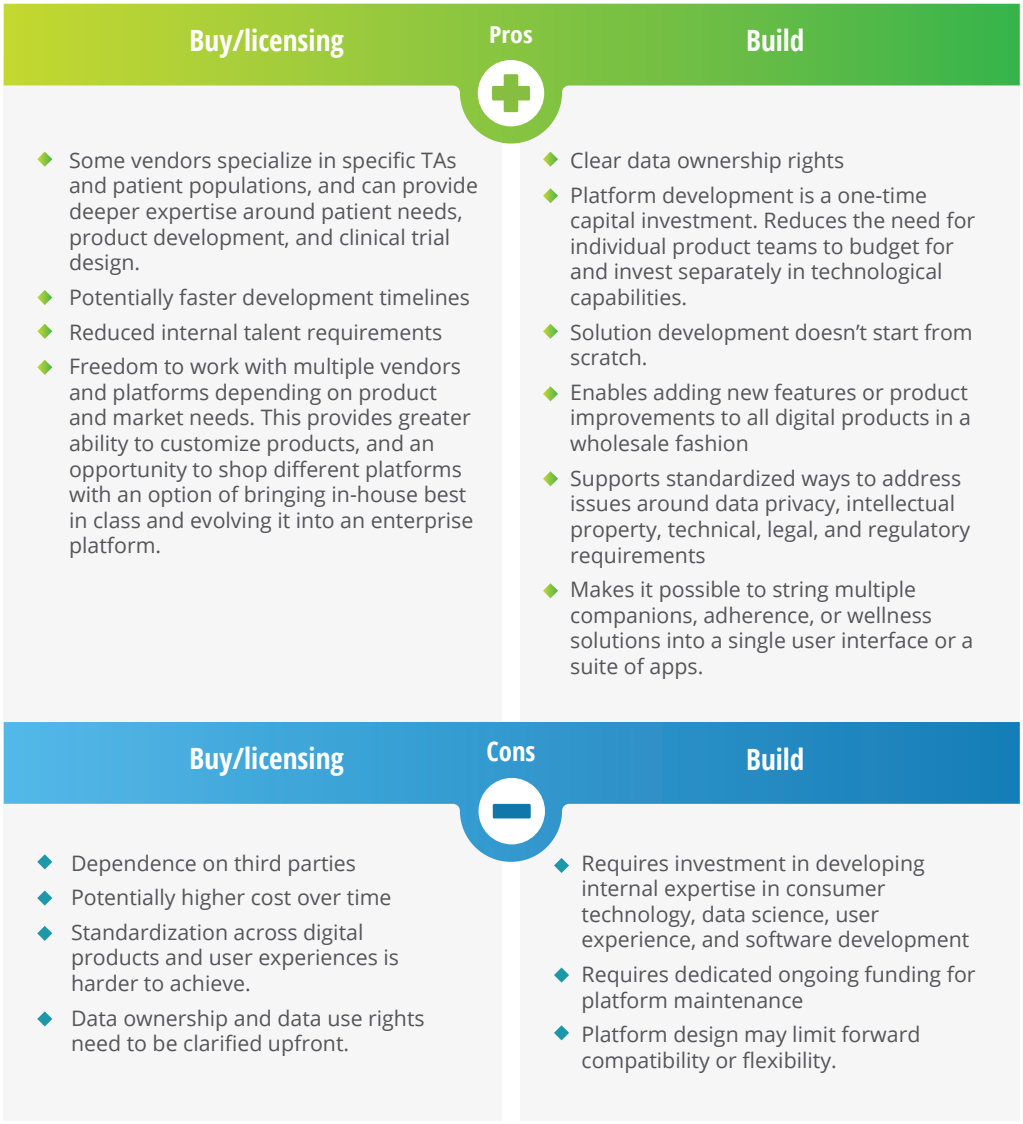
Selecting the right partner ensures efficiency, regulatory compliance, and speed to market. Our research has helped us identify important considerations that pharma and technology companies seek while selecting a partner to work with (figure 3).

At present, partnership deals mostly resemble in-licensing agreements. Technology partners may license their products to biopharma directly for a fixed fee per year, or payments could be tied to the achievement of specific project milestones (e.g., regulatory clearances). Though less common, licensing arrangements may include incentives tied to performance metrics, such as patient outcomes and adherence, or collection of clinical or health-economic data to support formulary positioning.

Some partnership deals involve leveraging pharma's marketing and distribution capabilities for commercial rollout. Contrary to expectations, such deals have not always been successful. Digital medicine products are a new modality for biopharma companies, and their commercial teams lack the experience, incentives, or training for engaging with physicians and payers on their economic and clinical value.

FIGURE 4

Considerations for build vs. buy



Source: Deloitte analysis.

BUY VS. BUILD

Most companies today leverage some platform capabilities and services from technology vendors to build digital companions. At one biopharma company we interviewed, the digital function has built a centralized platform in-house to enable product teams to develop digital companions for their brands.

As the number of digital products in their portfolio grows, biopharma companies could increasingly face the choice between building internal capabilities and reliance on external vendors. Either approach comes with pros and cons that we outline in the figure above.

Digital medicine products call for new approaches and capabilities

PREPARING FOR THE future of health built around patient centricity, prevention, and personalized therapies calls for biopharma to look at digital medicine products in a new light. Developing and commercializing such products require a clear articulation of how they fit within a company's product portfolio and the operating and business models needed to support that.

Based on our research and client experience, we recommend biopharma companies:

1. Formulate a vision around digital medicine products

Biopharma companies should articulate a vision of how they will position themselves within the digital medicine product ecosystem. Do they see themselves as preferred partners or leaders in the field? This is the essential starting place for guiding the short- and long-term strategy.

- **Consider alignment with the existing product portfolio and future pipeline.**
  - In the near term, our research suggests that digital companions are likely to become standard offerings around pharmaceutical products for conditions associated with complicated symptoms and comorbidities, requiring complex treatment regimens and monitoring of side effects.
  - A drug product's life cycle (e.g., approaching loss of exclusivity, prelaunch) and competitive position may inform the digital companion strategy.
  - In the long term, we expect some companies to explore digital therapeutics; a handful are developing these capabilities today, recognizing that digital therapeutics represent a new frontier of treatment in certain disease states like depression, anxiety, and chronic pain, and this list should grow over time. We also expect that digital companion capabilities will serve as an on-ramp to digital therapeutics.
  - We also envision alliances between pharma and medtech companies around development of devices that combine passive and active monitoring, drug delivery, and diagnostics.
- **Position within the consumer health journey.** Short term, companies are considering how to leverage digital medicine products in TAs where they already play. Long term, some companies are considering how to make digital tools and platforms the connective tissue from wellness and prevention to medical and surgical interventions to postacute care.

2. Play to their strengths and expertise

Pharma companies should apply their expertise in creating and commercializing evidence-driven products to their digital medicine product ambitions: regulatory science in the case of digital therapeutics and market access in the case of both digital therapeutics and companions. This is a significant competitive advantage against consumer tech companies that do not have this as a core competency.

3. Define an operating model that best supports their digital medicine product strategy

Effectively developing digital medicine products can be a steep learning curve for biopharma companies; comparisons to the development and commercialization of traditional medicines reveal just as many differences as similarities. We have outlined a few important considerations:

- **Distributed vs. centralized digital expertise**
  - Our research shows value in centralizing digital expertise. In most cases, we have found examples of concentrating digital resources within R&D, within the commercial function, or as a separate center of excellence. But bridging the traditional R&D and commercial silos remains a challenge.
- **Buy vs. build**
  - The vision will in part dictate decisions on whether to develop products in-house or partner with other stakeholders in the field. As digital medicine product offerings increase in number within a pharma company's portfolio and as biopharma's experience grows, we expect the cost benefit will shift in favor of insourcing.
  - We also expect that over time, standardization via an enterprisewide platform will be more beneficial than developing ad hoc or bespoke custom-built digital solutions. Given the shift to cloud computing, the cost structure can be elastic and scale with success and adoption.
- **Talent requirements**
  - Even with significant outsourcing, pharma companies should still develop an internal or contract talent pool with technical skills around cloud computing, AI, software development, cybersecurity, and data science.[28] These agile development teams should also include professionals who understand clinical measurement and patient and user experience and have access to legal, compliance, and medical device regulatory expertise. And most importantly, they should include individuals with a strong strategy and business acumen who can navigate technical, clinical, and business aspects, and facilitate conversations across multiple parts of the organization and with external partners.
  - Many of the existing talent and capabilities within organizations could be leveraged, including rich patient and provider insights and a deep understanding of the health care landscape. Strong connections to regulators and frequent touch points with payers could help drive conversations around holistic therapeutic solutions that include traditional pharmaceuticals, companions, and digital therapeutics.

4. Reinvent the product development life cycle

Incorporating digital medicine products successfully into a company's portfolio will require a rethinking of traditional drug development processes and:

- A deep understanding of unmet needs and pain points for patients and providers, as well as expertise in the features and development possibilities of digital medicine products.

- An iterative process with evaluation pilots and a feedback loop between user experience in the field and ongoing product improvements. This requires an agile build, test, and learn approach to product development and refinement, which will run on cycles that are different from current drug development models. Some of the initial investment and pilots will fail, but this experience will create learnings and a foundation for standing up robust digital capabilities.

  - Digital medicine products can be developed concurrently with drugs, but the timing of product design and availability must be positioned carefully within the standard regulatory and payer review and submission processes. The iterative nature of building software will require tighter **coordination between commercial, medical, and product development teams.**

- Development teams should leverage insights from commercial teams to identify where digital companion and digital therapeutics would be more useful, anticipate patient needs, and build products accordingly.

- Digital companion developers should be able to reuse or build upon digital tools used in clinical trials of the corresponding drug.

- Clinical development and digital teams should have access to internal and external libraries of validated electronic clinical outcomes assessments (eCOAs), such as those maintained by the Digital Medicine Society[29] or FDA.[30] There should be a process for identifying which digital endpoints or patient-reported outcomes in the company's core TAs could be available and appropriate for use in digital companions.

  - Access to such libraries could be an important starting point for developing digital therapeutics, as the efficacy of a digital therapeutic could be measured by the same or similar endpoints.

  - Commercial teams should have a basic understanding of eCOAs used in clinical development and which ones can be repurposed for digital companions and/or digital therapeutics.

5. Expand the traditional business models

With digital medicine products, the traditional commercialization and acquisition playbook may not be enough. Pharma companies may need to build relationships with new stakeholders or strengthen relationships with existing ones: e.g., care management or population health leaders at health plans; employers as payers or influencers; ambulatory providers as buyers, not just prescribers; and most importantly, patients as the chief health care customer. Identifying digital medicine investment opportunities should be part of business development activities.

- There may be opportunities to use traditional distribution channels in new ways, such as retail and specialty pharmacies, as well as less traditional ones like online prescription platforms.

- Generating demand from patients via DTC is an option for *digital companions*, whereas *digital therapeutics* require activation of all stakeholders: patients, providers, payers, pharmacists, and employers.

- Digital therapeutics could be a major change for providers and payers, as they will require adoption of a new standard of care. This will require large awareness and education initiatives, and pharma's customer-facing personnel will need to learn how to position digital products to these customers.

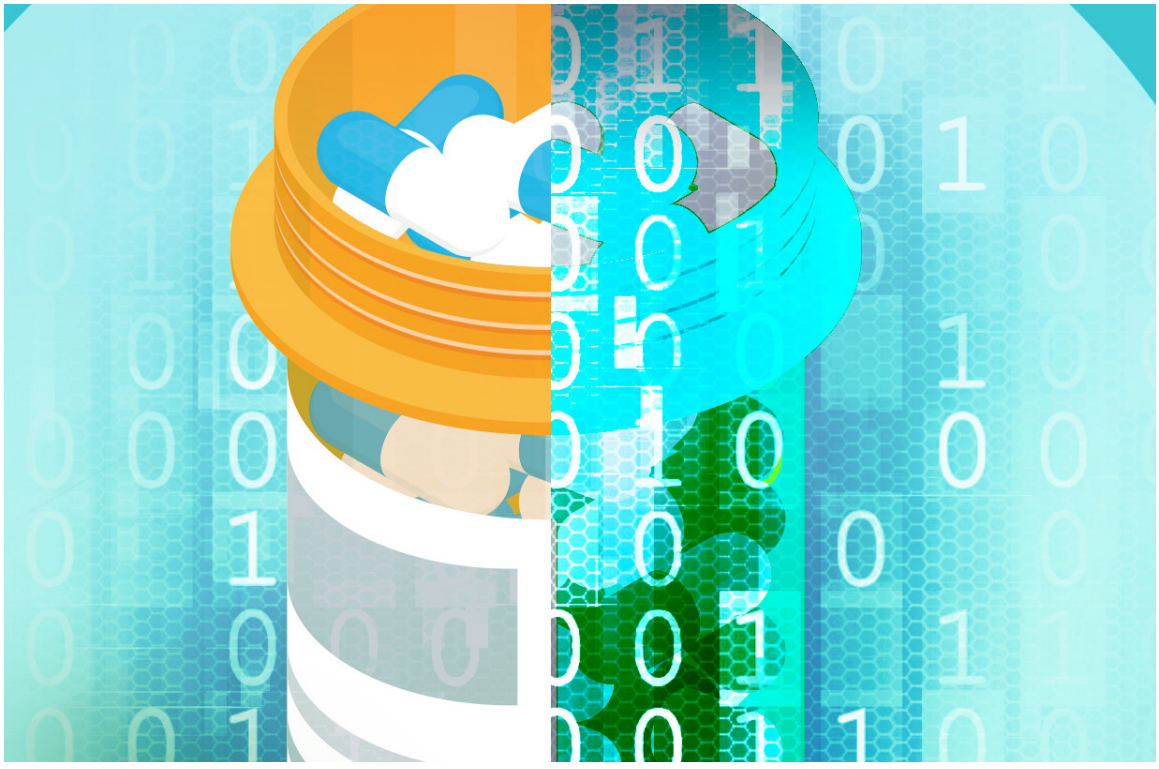
  - *Sales* needs to articulate value in relation to other products. There should be incentives to promote digital medicine products.

  - *Field medical* personnel will need to become comfortable explaining the development and science behind digital medicine products.

  - New types of *field-based* and *market access* roles may be required that specialize in digital medicine products.

  - New *customer support* functions and roles may be needed to support digital medicine products.

A future built around prevention, early detection, curative and personalized therapies is emerging. Developing a robust digital medicine product strategy is essential to succeed in this future, especially as evidence continues to grow as to their efficacy in improving outcomes and quality of life. Our research shows that although it may be early days, the age of digital medicine products is here. Life sciences companies that can identify a clear place for themselves within this burgeoning ecosystem should see a competitive advantage with their customers, demonstrate more value to the health care system, and ultimately, deliver better outcomes for patients.



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About the Digital Medicine Society (DiMe)

Founded in 2019, the Digital Medicine Society (DiMe) is the first professional organization for experts from all disciplines comprising the diverse field of digital medicine. Together, we drive scientific progress and broad acceptance of digital medicine to enhance public health.

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