

EXECUTIVE SUMMARY

Connected health has been the long-held panacea for reviving the healthcare sector, guiding it smoothly through a transition to the digital age. Pharmaceutical companies, healthcare practitioners, technology companies, government officials, academics, and other stakeholders had been keenly discussing the digital-health opportunity even before the unveiling of the Affordable Care Act in the US in 2010, which established outcomes as an important measure of care and reimbursement and incorporated digital technologies as a medium for offering the physically and socially constrained greater access to care. Given the legacy challenges the life sciences sector faces – from regulatory issues to sluggish innovation to drawn-out approval processes – transformation of healthcare has been slow to get off the ground. In contrast, the behaviors of consumers and patients have shifted dramatically over the past 18 months in reaction to the COVID-19 pandemic: openness to the adoption and use of digital technologies in a healthcare setting has accelerated rapidly. Can biotechnology and pharmaceutical (biopharma) companies capitalize on this momentum to transform and scale their connected health portfolios? Are we finally approaching the tipping point at which connected health is sufficiently mature to drive lasting healthcare transformation?

The results of our research reveal that most biopharma companies are still developing their connected health models, and that overall maturity of connected health portfolios remains low. Nevertheless, ambitions for connected health are lofty. Eighty-four percent of biopharma respondents in our survey said that the market opportunity for connected health exceeds that offered by their traditional drug businesses. Moreover, biopharma respondents anticipate connected health products will represent approximately 13% of their organizations' total revenue in five years' time. In terms of improvements in standards of care and patient outcomes, as well as revenue projections, many regard connected health as the most viable long-term model for the sector.

To support this dynamic, we highlight six key actions biopharma companies can take to close their maturity gap and scale their connected health products and services effectively. Defining a connected health strategy aligned to established portfolio plans is critical for biopharma companies seeking internal buy-in and investment. Designing connected health products to drive measurable value and health outcomes will simultaneously demonstrate the clinical efficacy and commercial viability of connected health products to payors, promoting confidence and, by extension, reimbursement coverage. Centralizing the governance, operating model, and financial structures for connected health will increase autonomy of connected health teams, allowing them to work faster and in a more agile, collaborative manner, and also allow for more coordination in the regulatory approval process. On a wider scale, building a data ecosystem that promotes data sharing and interoperability within, and outside the organization, upskilling talent in data, behavioral science, and agile development, and building an ecosystem that provides guardrails while it embraces open innovation will allow biopharma companies to scale their products and services at speed in the new model, establishing connected health as the template for future healthcare.



INTRODUCTION

Attempts to introduce innovation to the healthcare sector have, historically, been hindered by cost, compliance, regulatory constraints, reimbursement issues, and cultural barriers. Connected health – which sits at the intersection of digital and traditional care – is regularly discussed around the world as a way to harness the power of new technology to improve patient engagement and health outcomes. In the US, connected health began its rise to prominence with the passage of the Affordable Care Act (ACA) in 2010; the ACA showed a revolutionary approach to simultaneously improving quality of care, lowering costs, and expanding coverage. It established outcomes as a key measure of care and reimbursement. It also posited "telehealth" (the distribution of diagnostic and information services using information and communication technologies) as a way by which to support greater access for patients, signaling an openness to the use of digital technologies and, in the process, laying the groundwork for innovative healthcare frameworks.1

The growth of connected health – and, with it, the mitigation of some of the long-standing barriers to healthcare transformation – has been accelerated by the COVID-19 pandemic, particularly through the rise in the use of telemedicine, with patients increasingly preferring remote over in-person care for reasons of convenience, ease of scheduling, and safety concerns, among others. Our 2020 research on consumer health behaviors revealed that consumers increasingly demand digital health and "low-touch" care options.²

Market trends, including the push towards patient-centered solutions, the increasing cost of chronic disease management; the shift towards value-based performance in the US (i.e., incentive payments to providers based on the quality of care); and the need to extend the lifetime of mature brands, particularly at large drug manufacturers, are also driving demand for connected health. The size of the digital health market is set to surpass \$426.8 billion by 2027.³ Investment funding in digital health startups hit \$57.2 billion in 2021, up 79% from 2020.⁴ Moreover, the global digital therapeutics market is expected to grow to \$14.5 billion by 2027.⁵

Given the legacy challenges in the sector and the fact that, globally, companies are still in the early stages of maturing their connected health portfolios, we wanted to explore how biotechnology and pharmaceutical (biopharma)

organizations can more effectively manage and grow their connected health portfolios. We sought to identify the most significant challenges and barriers to maturity in developing a connected health portfolio and to understand the strategic objectives of biopharma companies and the governance structures required to support connected health, as well as to pinpoint the values and benefits that connected health products can bring to biopharma companies.

To address these questions, we surveyed 523 life sciences executives (representing 166 companies) within the pharmaceutical and biotechnology sectors in seven countries: France, Germany, Italy, Japan, Switzerland, the UK, and the US. We also conducted in-depth interviews with life sciences executives to complement the quantitative insights. Our questionnaire explored companies' connected health strategies and governance structures; capabilities; product development and launch processes; benefits and use cases; and key challenges in building a connected health portfolio. Please refer to the methodology for more details on the survey.

In this report, we focus on five key areas:

- 1. The nature and benefits of connected health
- 2. The level of adoption of connected health among biopharma companies and the most promising use cases
- The top challenges that must be overcome to fulfill the ambitions of connected health
- 4. How connected health is set to revolutionize healthcare and drive business value
- Key recommendations for how biopharma companies can close the maturity gap and scale their connected health portfolios.

79%

Growth rate of investment funding in digital health startups from 2020 to 2021.



WHAT IS CONNECTED HEALTH AND HOW DOES IT BENEFIT PATIENTS?

01

For the purposes of this research, the definition of connected health covers a wide spectrum of digital health products and services, from digital wellness products such as consumer wearables to clinically validated solutions such as digital companions, digital therapeutics (DTx), and combination DTx, including Software-as-a-Medical Device (SaMD).

Digital therapeutics (DTx) promise the highest positive impact on patient health

We classify connected health products into four broad groups: digital wellness, digital companions, digital therapeutics, and combination digital therapeutics. One key differentiator between these groups is whether they require clinical evidence to support their quality and effectiveness and to obtain approval from regulators (see Figure 1).

An executive at a multinational healthcare company, comments: "Digital therapeutics are the 'holy grail' in digital healthcare. The rewards are expected to be high, both in terms of financial and patient outcomes. It will be critical that countries put in place the appropriate reimbursement processes for digital therapeutics products. This will ensure that the healthcare system can reward this type of innovation." In June 2020, the FDA approved the first-ever prescription treatment delivered through a video game. Akili Interactive's EndeavorRX aims to improve attention function in children with attention-deficit/hyperactivity disorder (ADHD).6

Patients stand to benefit from connected health throughout their journeys

Our research reveals that patient engagement and satisfaction are critical patient outcomes for connected health. The overwhelming majority (97%) of biopharma respondents say that their company has realized or aims to realize increased patient engagement and satisfaction from its connected health product portfolio. New treatment possibilities (95%) and early diagnosis and detection of disease (94%) follow as core patient outcomes that respondents believe connected health can or has achieved. By harnessing new digital technologies, healthcare professionals (HCPs) can meet patient needs for a more convenient, personalized healthcare experience. Our 2020 research revealed that consumers demand digital-health and remote-care options. In fact, nearly half (46%) of all consumers (and 56% of those aged 23 to 38) said they were comfortable with using technology to manage their health today.⁷ Connected health will also allow patients to:

• Be more engaged in their own healthcare decisions and take more responsibility for their own care.

Launched in July 2021, Happify Health's Ensemble is a prescription digital therapeutic to help diagnose and manage major depressive disorder and generalized anxiety disorder. It is a digital platform accessible via a smartphone or computer and teaches patients new skills and coping habits. Offered as a supplement to standard care, the Ensemble app empowers patients to better manage their anxiety and depression by letting them be in control of their treatment.8

THE DEFINITION OF CONNECTED HEALTH

Connected Health Consumer Digital Value-Based Outcomes-Based Digital Health **Digital Health Digital Wellness Digital Companions Digital Therapeutics Combination Digital** Therapeutics Technologies, platforms, Low-risk, evidence-based Clinically validated, and and systems that engage software and/or hardware regulated software Clinically validated, and consumers for lifestyle, products that work in (SaMD) that delivers regulated combination of conjunction with wellness and evidence-based software, drug and/or health-related purposes, traditional products and therapeutic interventions device, that delivers including administrative. measure and/or intervene and measurable health evidence-based in the service of human outcomes for the therapeutic interventions health. prevention, management, and measurable health or treatment of a medical outcomes for the condition. prevention, management, or treatment of a medical condition. Clinical evidence and regulatory approval required, but not always evidence-based or subjected to clinical Health and wellness Product examples • Fitness trackers Remote patient monitoring tools or reminder apps

Source: Source: Transforming Connected Health: From experiment to enterprise profit center, Capgemini Life Sciences and Healthcare, 2021.

One impact of increased patient empowerment can be improved adherence to therapies. A director of medical affairs at a global pharmaceutical company, says: "Our vision for connected health is to develop digital solutions to improve the care of the patient and the role of the physician. We want to support the implementation of our drugs appropriately, and to improve patient adherence so they can better manage or treat their illness."

• Receive improved access to care in times and locations convenient to the patient, via remote care. In October 2021, the FDA approved a virtual-reality (VR) treatment for children with the visual disorder amblyopia, or lazy eye from digital therapeutics startup Luminopia. The VR headset allows patients to watch their favorite children's TV shows and movies to improve their vision. Expected to be launched in 2022, the VR treatment will allow patients and their caregivers the convenience of treatment at home.⁹

One effect of the pandemic has been an improvement of access to care through the digitalization process, as an executive at a multinational healthcare company believes: "During the COVID-19 pandemic, not only have we seen increased patient-to-doctor connectivity but also a decentralization of care – the ability to bring in knowledge from different locations to make healthcare accessible in areas where it was not accessible before. I think these trends will continue in the future and we will see more innovation driven through digitalization in the healthcare system."

• Benefit from improved coordination of care as patient data can be automatically sent to physicians and updated in medical histories. Apple Watch offers arrythmia detection features. It is cleared by the FDA as Class II software as a medical device. The high and low heart rate notifications alerts users when their heart rate remains above or below a chosen beats per minutes. The irregular rhythm notification feature looks at the user's heartbeat to check for an irregular rhythm that might be suggestive of atrial fibrillation (AFib). Apple Watch Series 4 or later can also generate an electrocardiogram through the ECG app. All data can be easily shared with the user's doctor, allowing for improved coordination and transparency.¹⁰

97%

of biopharma executives say increased patient engagement and satisfaction are critical patient outcomes for connected health

A health economics and outcomes research (HEOR) executive at a global pharmaceutical company, sees data as a driving force to patient benefits. "In terms of patient outcomes, a key goal for connected health is to collect more relevant and timely data. Patients could avoid coming back every week for follow-up visits with their clinicians. Incorporating automated or patient-reported outcomes in health economics and outcomes research, along with registration trials and even up to phase four clinical trials will be critical."

Along all steps of the patient journey, from preventive care through diagnosis, treatment, and monitoring and follow-up, patients will benefit from the use of digital health technologies. There are examples of approved connected health products and services for each step of the patient journey (see Figure 2).

1. Prevention

Novartis and Propeller

3. Treatment

- Wearable sensor device provides real-time readings
- regular intervals

Abbott Laboratories' Lingo

- Wearable biosensor technology
- Focuses on markers for metabolic
- Tracks glucose, ketones, lactate, and alcohol levels on smartphone
- Announced but still in development

AliveCor's KardiaMobile

- FDA-cleared and CE marked, medical-grade EKG recordings
- Detects six common arrhythmias through fingertip sensor
- Track data over time or email recordings to doctor for review

Given Imaging's (now Medtronic) PillCam COLON

2. Diagnosis

- FDA approved
- Minimally invasive alternative to colonoscopy
- Power source, light source, and two micro-cameras in one pill with 10h battery life

Health's Enerzair Breezhaler asthma medication

- EC approved
- Sensor attached to inhaler
- Delivers medication data to app on patient's smartphone
- App manages dosage reminders and adherence

Pear Therapeutics' reSet and reSet-O mobile app

- FDA approved
- Prescription digital therapeutic
- For use with substance use disorder and opioid use disorder
- Helps retain outpatient treatment status

Applied VR's Ease VRx

- FDA approved
- Prescription-use immersive VR system
- Treats chronic back pain
- Teaches breathing exercises

Click Therapeutics' Clickotine mobile app

- Clinically-validated digital smoking cessation program
- Offers personalized support and messaging
- Engages family and friends for real-life support to quit

Abbott's FreeStyle Libre 2 Continuous Glucose Monitoring system

- FDA and EC approved

4. Monitoring and

Follow-up

- Collects glucose levels at
- Links to smartphone app

Voluntis's Insulia for type 2 diabetes

- Prescription-only medical device
- Combines patient mobile app and HCP web portal
- Recommends insulin doses based on treatment plan and blood-sugar values
- Remote monitoring by HCP

Sonde Health's respiratory health mobile app

- Detects and monitors for symptoms of COVID-19, asthma, COPD, and other pulmonary conditions
- Helps reduce spread and improve overall health through early detection
- · Uses voice technology

Source: Company websites, company press releases, news articles, and the Digital Therapeutics Alliance. *FDA = US Food and Drug Administration; EMA = European Medicines Agency; EC = European Commission.

THESE ARE STILL EARLY DAYS FOR CONNECTED HEALTH

02

Maturity of the connected health enterprise is low

Our research shows that most biopharma organizations are still at the planning stage when it comes to implementing connected health products and services. In fact, 84% of biopharma executives said their company is still in the process of strategizing their approach to connected health (see Figure 3). All companies that are testing products or have approved products have more than \$1 billion in revenue, with more than \$20 billion representing the largest share (46%).

84%

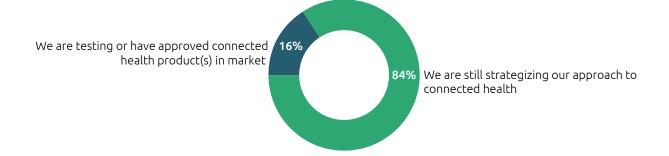
of biopharma executives say their company is still strategizing their approach to connected health



Figure 3

THE VAST MAJORITY OF BIOPHARMA COMPANIES ARE STILL DEVELOPING THEIR CONNECTED HEALTH STRATEGY

% of respondents who agree with the statements



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

Many biopharma respondents said that their organization's overall maturity in connected health is "emerging" (see Figure 4). Only a quarter of respondents said their organization is mature in key areas such as portfolio strategy, product design, and product development. Many biopharma companies are playing "catch-up" on leading integrated connected health operations.

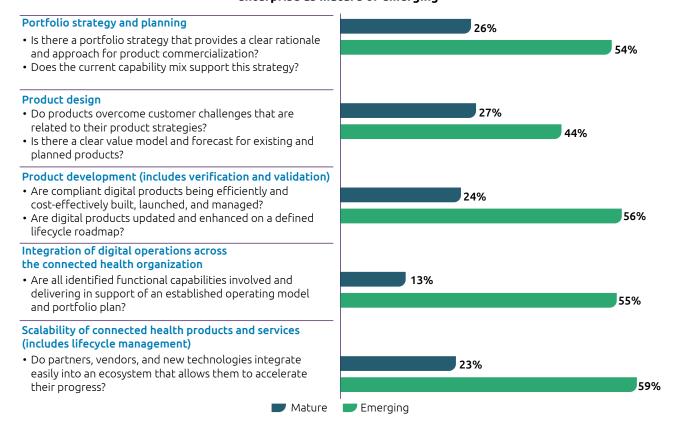
Segmenting this data by company revenue reveals that larger companies have a maturity advantage across all five areas we tested, especially among those with more than \$20 billion in revenue. For example:

- 49% of biopharma companies with more than \$20 billion in revenue said they are mature in portfolio strategy and planning compared to only 17% of companies with less than \$1 billion.
- 43% of biopharma companies with more than \$20 billion in revenue said they are mature in scaling connected health products and services compared to only 10% of companies with less than \$1 billion.

Figure 4

THERE IS A LACK OF MATURITY IN CONNECTED HEALTH

% of respondents that define the maturity of their organization's connected health enterprise as mature or emerging



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents; Capgemini Research Institute analysis.

Diagnosis and monitoring are underserved areas

Among respondents who are testing connected health products or who have an approved product in market, 62% said their company's connected health portfolio includes products covering the treatment step in the patient journey. Over half (56%) said their portfolio includes products to support the initial prevention step. Only 13% of respondents said their company's portfolios target the diagnosis or monitoring phases (see Figure 5). The low percentage of respondents citing diagnosis and monitoring is likely the result of a focus that pharmaceutical companies have had on their traditional areas of expertise such as treatment. Connected health products targeting diagnosis and monitoring represent areas of opportunity for pharmaceutical companies and can be a way to support the full care continuum, and not solely treatment or prevention.

A HEOR executive at a global pharmaceutical company says digital health is more advanced in commercial than in clinical operations: "In my estimation, digital health is more advanced from a commercial perspective than it is from a clinicaltrial perspective. I've introduced digital health colleagues to the clinical operations team so [the latter] can see and understand at least one provider of connected health technology. Right now, our clinical trials are done in the typical, old-fashioned way."

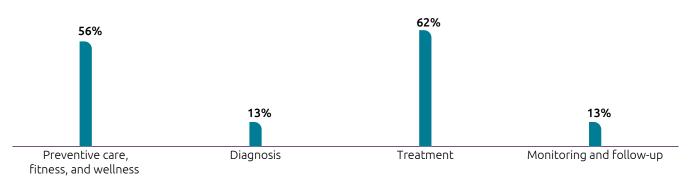
56%

of biopharma executives said their connected health portfolio includes products to support prevention

Figure 5

THERE IS A FOCUS ON BOTH PREVENTION AND TREATMENT

Connected health products by patient journey among companies currently testing products or with approved products in market



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 84 biopharma respondents who currently have connected health product(s) approved at market or who are currently testing/developing connected health product(s).

Digital and technology capabilities are emerging

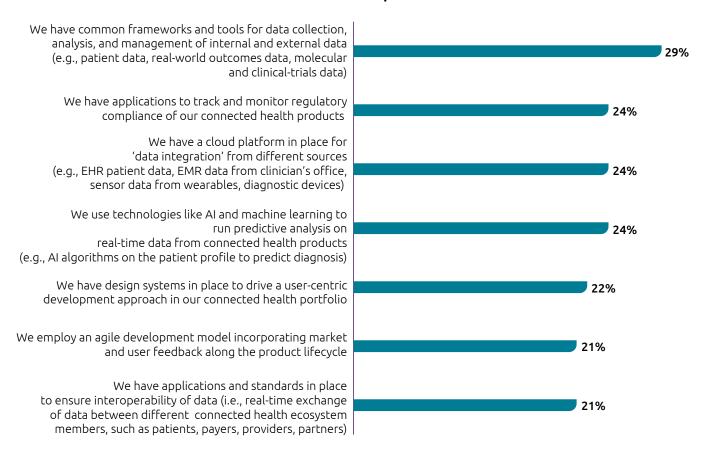
Less than a third of all biopharma respondents said their organization had the digital and technology capabilities required for connected health. For example, only 21% of biopharma respondents said their company has data interoperability and agile development capabilities (see Figure 6).

When segmenting this data by the maturity level of biopharma companies, companies who were early movers in connected health have a significant maturity advantage. Unsurprisingly, more mature providers of connected health (i.e., those with approved products, or those who are currently testing products) have far more capabilities than those companies who are currently developing their strategy for connected health.

Figure 6

DIGITAL AND TECHNOLOGY CAPABILITIES ARE LOW

% of respondents that agree with the following statements on their organization's connected health capabilities



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

Collaboration capabilities are under development

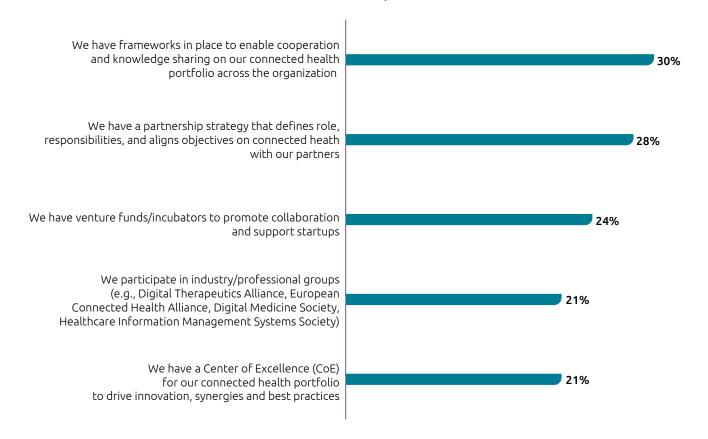
Similarly, when it comes to the capabilities required to operate in collaborative connected health partnerships, less than a third of all biopharma respondents said their organization possess those capabilities. For example, 30% said their company has frameworks in place to enable cooperation and knowledge sharing (see Figure 7). Those respondents who said their organization has approved connected health products in market, or are currently testing or developing them, are far more advanced than those respondents who said their organization is still strategizing its approach.

Yannis Pandis, director of digital partnerships at Johnson & Johnson, comments: "[The ability to create] good partnerships with companies that have the experience and infrastructure to run global trials is a very important capability. Otherwise, the risk is you will be doing only one pilot in one country, which you can support [only] minimally."

Figure 7

MOST COLLABORATION CAPABILITIES ARE STILL DEVELOPING

% of respondents that agree with the following statements on their organization's connected health capabilities



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

Most connected health use cases are planned for implementation within five years

We explored the implementation maturity of nine selected connected health use cases among biopharma respondents to assess which developmental stages companies had reached:

- Developed proof of concept
- Are running a pilot in clinical research for proof of value
- Are in regulatory review
- Have commercialized and rolled out the product in market.

With the exception of a mobile app and remote patient monitoring, less than 20% of biopharma executives said their company had developed a proof of concept for any use case (see Figure 8). Over half of biopharma executives said their company is planning to initiate the below use cases in the next five years:

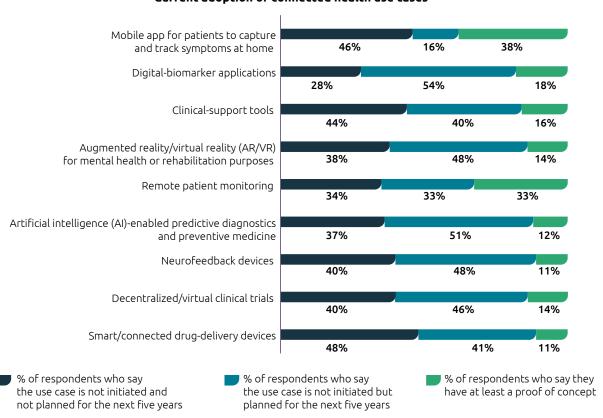
- Digital biomarker applications (e.g., wearable biosensors in the forms of gloves, clothing, or embedded implants to continuously track patient health) (54%)
- Artificial intelligence (AI)-enabled predictive diagnostics and preventive medicine (51%).

By revenue size, larger companies, given their maturity advantage, are not surprisingly further along in their development of connected health use cases. A greater share of companies with \$20 billion in revenue compared to smaller companies are at the proof-of-concept stage or beyond for each of the use cases we analyzed. For example, 43% of biopharma respondents at companies with more than \$20 billion in revenue say they are beyond proof of concept for digital-biomarker applications, compared to only 6% of companies with less than \$1 billion.

Figure 8

LESS THAN 20% OF RESPONDENTS HAVE TAKEN THE CONNECTED HEALTH USES CASES BEYOND PROOF OF CONCEPT

Current adoption of connected health use cases



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

Indira Jain-Figueroa, product director of digital health at AstraZeneca believes the oncology field presents promising opportunities for the development of connected health use

cases: "Many oncology trials are set up so patients have to come to a clinic every cycle. It is a cumbersome process for someone who is going through chemo and who really does not feel well. This is where remote monitoring using consistent data flows comes into play. The doctor could proactively review [data from] wearables or other devices [as required] without the patient needing to leave home."

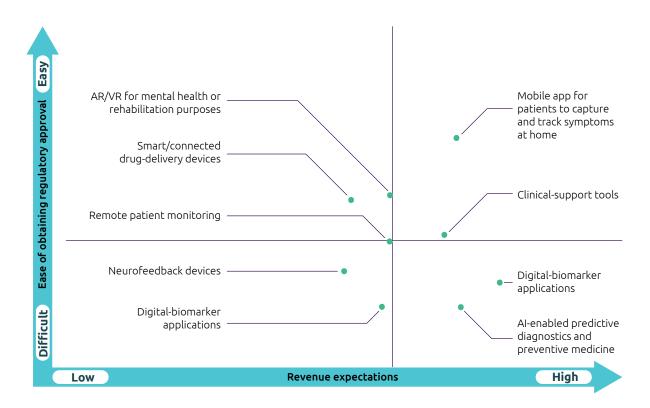
Finnish digital health company Kaiku Health offers a mobile app that guides cancer patients through treatment and recovery. Patients track their symptoms and receive personalized feedback and education. Self-reported data is transmitted to the patient's care team, allowing for improved doctor-patient communication between treatment visits.¹¹

Certain connected health use cases have high revenue expectations

We asked those biopharma respondents who said their company has (at minimum) a pilot with proof of value for any of the use cases we analyzed for their views on the ease of obtaining regulatory approval and their revenue expectations for these use cases. A large majority (81%) believe digital biomarker applications (e.g., wearable or implanted biosensors that continuously track patient health) have high revenue expectations, yet only 25% consider gaining approval from external regulators "easy" (see Figure 9).

Figure 9

RELATIVE EASE OF APPROVAL AND REVENUE EXPECTATIONS, BY CONNECTED HEALTH USE CASE



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 14–66 biopharma respondents who said their company was at the implementation maturity stage of 4 = pilot with proof of value, 5 = clinical research, 6 = regulatory review, or 7 = commercialized/rolled out to market for at least one of the nine use cases. *Due to the small sample size for some use cases, results are purely directional in nature.

CHALLENGES MUST BE OVERCOME FOR CONNECTED HEALTH TO FULFILL AMBITIONS

03

We explored the top challenges faced by biopharma companies when developing, managing, and growing connected health portfolios.

Security, technology, and regulatory are major roadblocks

Over half of respondents (58%) said that security vulnerabilities, such as developing compliant software and managing the lifecycle is the top challenge their organizations face in development, launching, and/or scaling connected health products and services (see Figure 10). Regulatory approval in terms of the product type (e.g., digital therapeutics having different requirements than traditional therapies) is a top challenge for 48% of respondents.

By maturity level of biopharma companies, the regulatory approval process is a greater challenge for companies still strategizing their approach to connected health (50% versus 32% among those with approved products). It appears that the uncertainty of the regulatory process might be holding some companies back, and for those mature companies, once they understand the regulatory guardrails, they are better positioned to replicate the process. In addition, data and analytics is a greater challenge to companies with approved products (48%) than companies still developing their strategy (32%), suggesting once products are launched, companies might be more acutely aware of shortcomings and roadblocks around data capabilities.

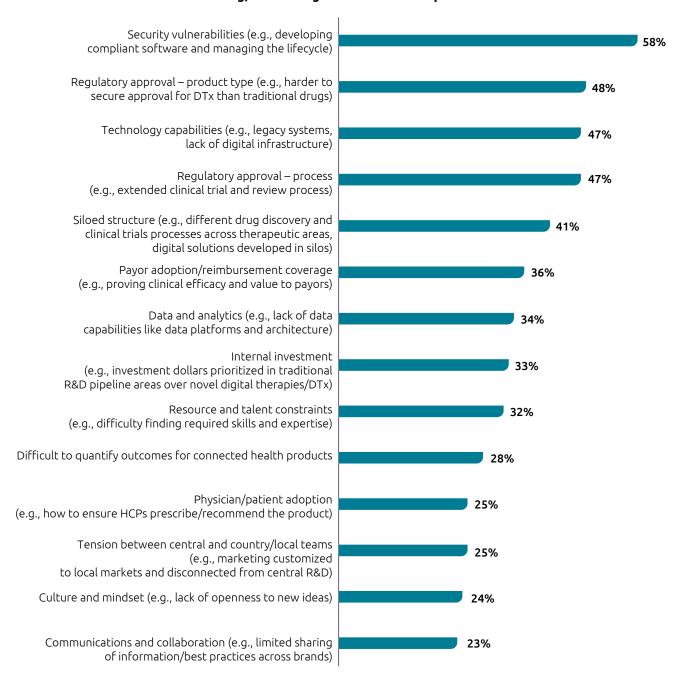
Similar trends exist by revenue size given that those with a maturity advantage tend to be the larger companies:

- 45% of biopharma companies with more than \$20 billion in revenue cite security vulnerabilities as a top challenge compared to 69% of companies with less than \$1 billion.
- 30% of biopharma companies with more than \$20 billion in revenue cite the regulatory approval process as a top challenge compared to 58% of companies with less than \$1 billion.

We also asked biopharma executives how their company funds connected health ventures and how they measure success in the product-development process. We found that:

- Most companies do not use a central funding system for connected health products and services
 - 54% said the CFO or the finance director allocates funds to connected health from their budget
 - 34% said the management Board or CEO allocates the funds
 - Only 7% said the CDO or the digital health lead allocates funds.

% of respondents ranking the below among the top five critical challenges in developing, launching, and scaling connected health products



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

- Eight out of 10 companies do not have a structured process for managing and measuring the success of connected health offerings
 - 20% of respondents said that connected health product prototypes must exceed an ROI threshold before they will be "green-lit"
 - Only 17% said they have a defined stage-gate process (with various points at which a decision is made as to whether to proceed) for developing connected health products.

Satisfying regulations and compliance requirements were also cited as top challenges by interviewees. AstraZeneca's Indira Jain-Figueroa comments: "In the pharmaceutical sector, the digital health space is not appropriately regulated. I believe some of the data-protection laws are outdated and the fact that there is a disparity globally makes it unbelievably challenging."

Fabio Guarna, commercial operation director at Organon, a global healthcare company focused on women's health agrees with this sentiment: "One of the biggest challenges is related to compliance and privacy. When we think about new services that we want to add to our drugs [...] the first step to launching a new service is understanding and clarifying how we can deal with data privacy."

There is a critical technical skill gap

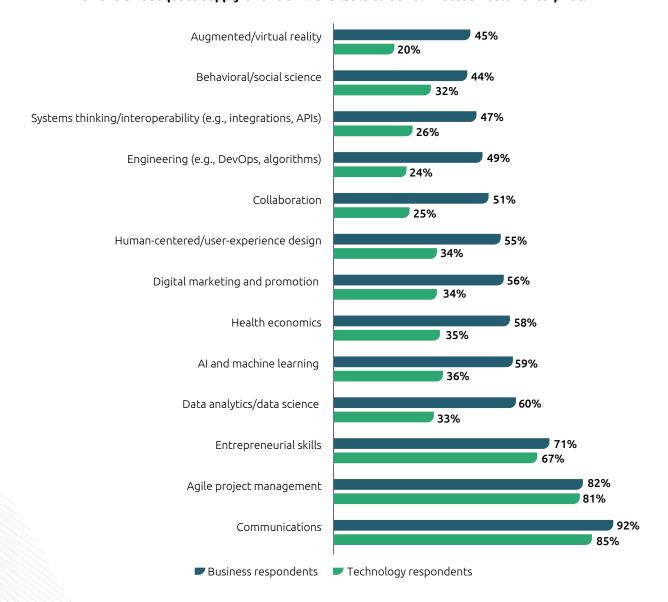
We assessed whether there is a gap in the skills required for developing and managing a connected health portfolio, across biopharma executives working in technology and business roles. The skills that are in most plentiful supply across the two demographics are concentrated in the areas of softer managerial skills, such as communications and agile product management. However, business respondents see their organizations as more solidly supplied across the range of skills, whereas their technology counterparts

do not in terms of the more technical and analysis-based skills. Augmented/virtual reality, systems thinking and interoperability, engineering, and human-centered design are the top technical skills with the greatest shortage (see Figure 11).

Johnson & Johnson's Yannis Pandis, believes the biopharma sector needs more agile, adaptable talent with a broader outlook: "It requires a shift in mindset to move into the pharmaceutical space because you have to think beyond your scientific, IT, or mathematical training. One must think in a much more integrated, broader fashion in pharma."

Regulatory and market-access skills are especially important, agrees Milena Saleh, global director of digital health at Sanofi: "The skills around regulatory are very important. For example, how to structure the dossier or how to approach the product and the intended use. Market-access skills are also critical to understand within which framework a product may fall once developed and what pharmacoeconomic model and data can be used during the development process."

% of respondents in technology and business that agree with the statement: "We have an adequate supply of this skill available to our connected health enterprise."*



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents; N = 372 business respondents; N = 87 technology respondents.

^{*}Business comprises respondents working within digital health, R&D, innovation, therapeutic area/product leadership, production/manufacturing, clinical research, finance and administration, clinical trials departments/functions; Technology comprises respondents working within information/digital technology and data and analytics departments/functions.

THE CONNECTED HEALTH ECOSYSTEM

We examined the types of organization with which biopharma companies are electing to partner on connected health. Approximately 40% of respondents said their company partners with organizations for strategy, design, or implementation and health tech startups. Roughly a third said they partner with IT services provider for data or cloud platforms (see Figure 12).

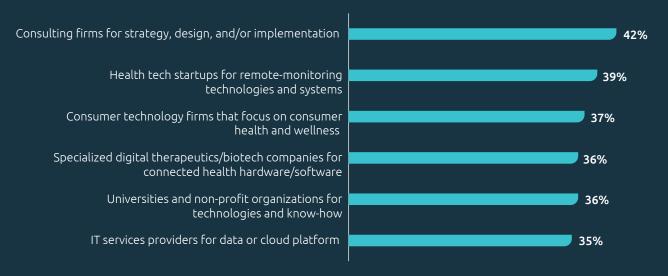
In examples of new technology being brought into a new therapeutic medium via collaboration, in 2019, Sanofi announced a partnership with US-based startup Happify Health, to develop prescription digital therapeutics to treat anxiety and depression among people with multiple sclerosis.¹² In January 2022, Pfizer announced a partnership with Stockholmbased digital therapeutics company Alex Therapeutics to create new digital therapeutics utilizing AI and evidence-based psychology. The partnership will first focus on a digital therapy treating nicotine addiction via smartphone.13

Indira Jain-Figueroa of AstraZeneca details a key challenge for finding the right external partners: "It is very hard to find the right combination of technology expertise and clinical-trial experience. You might want to use [a potential partner's] technology but when you start talking about the things needed for the regulatory bodies or the IRB [Institutional Review Board], they are a deer in headlights. You also find the other extreme: companies that understand how to do all the regulatory pieces, but their technology is old and outdated. There's no good intermediate company."

Figure 12

STRATEGY, DESIGN, OR IMPLEMENTATION ARE THE MOST COMMON MOTIVATIONS FOR CHOOSING PARTNERS

% of respondents that agree with the following statements on their organization's connected health capabilities



Source: Capgemini Research Institute, connected health survey, October-November 2021, N = 523 biopharma respondents.



CONNECTED HEALTH IS SET TO REVOLUTIONIZE HEALTHCARE AND DRIVE BUSINESS VALUE

04

Connected health has long been discussed as a way to improve patient outcomes and drive business value. While there are prominent examples of connected health products and services on the global market, many pharmaceutical companies are still in the early stages of development. How close are we to the technological tipping point that will allow connected healthcare to drive transformation of the sector? Our research reveals the potential of connected health and the ambitions of those who have recognized that potential.

Many believe that connected health will change healthcare

Nearly all biopharma executives (99%) agree that connected health will revolutionize healthcare by creating new treatment pathways, and that it will make healthcare more personalized and integrated This consensus remains true across countries, areas of focus (i.e., business, commercial, or technology), and seniority (i.e., whether they are managers or executives).

The ability for connected health to change healthcare radically will be impacted by patient uptake. Most respondents in our survey also believe that patients are accepting of connected health, with 71% agreeing that patients are willing and comfortable using connected health products and services. Our consumer health research

supports this, with 56% of millennials saying they were comfortable with the growing use of technology to manage their health. An executive from a multinational healthcare company believes the pandemic has been a key accelerator for connected health: "COVID-19 has been the biggest driver in moving digitalization forward in the healthcare industry. It has overcome barriers that have existed in most of the mature healthcare markets."

99%

of biopharma executives agree that connected health will create new treatment pathways and make healthcare more personalized and integrated One area that is already being transformed is mental health. Our research on consumer health behaviors found that the COVID-19 pandemic has exacerbated consumer concerns over their mental health, with nearly half (48%) of millennials saying that they are worried about their mental health deteriorating.¹⁵ Within the fragmented US healthcare system, mental health treatment has been hindered by issues of access, particularly in rural communities and underserved populations.¹⁶ Digital therapeutics have the potential to address inequities in healthcare access, by offering mental health treatment to patients where they are, precisely when they need it. Swedish pharmaceutical company Orexo gained FDA approval in 2020 for Deprexis, an online cognitive behavioral therapy to treat depression. It interacts with patients like a live therapist and can be accessed 24/7 on any device.17

Connected health products are also reaching underserved or at-risk groups challenged by mental health issues, such as older adult populations. US-based start-up Rendever uses its virtual reality platform in nursing homes and assisted living facilities to help seniors overcome social isolation and depression through shared, immersive experiences. The company is now in clinical trials to further research the impact of virtual reality across various levels of cognitive impairment on memory improvement.¹⁸

The perceived market opportunity for connected health is extensive

Eighty-four percent of biopharma executives said that the market opportunity for connected health exceeds that offered by their traditional drug businesses. This rises to 97% among respondents in Europe (see Figure 13). AstraZeneca's Indira Jain-Figueroa comments: "I think the opportunities in connected health are enormous – you just have to do it right."

84%

of biopharma executives say that the market opportunity for connected health exceeds that offered by their traditional drug businesses

Figure 13

CONNECTED HEALTH OFFERS BIGGER OPPORTUNITIES

% of respondents who agree with the statement: "The market opportunity for connected health is bigger than our traditional drug business."



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents; N = 281 biopharma respondents in the US; N = 182 biopharma respondents in Europe.

Revenue projections for connected health are significant

We asked respondents to estimate the percentage of their organizations' total revenue that would be represented by connected health products in five years' time. Overall, they set the figure at around 13% (see Figure 14).

Figure 14

CONNECTED HEALTH WILL REPRESENT A GROWING PROPORTION OF REVENUE

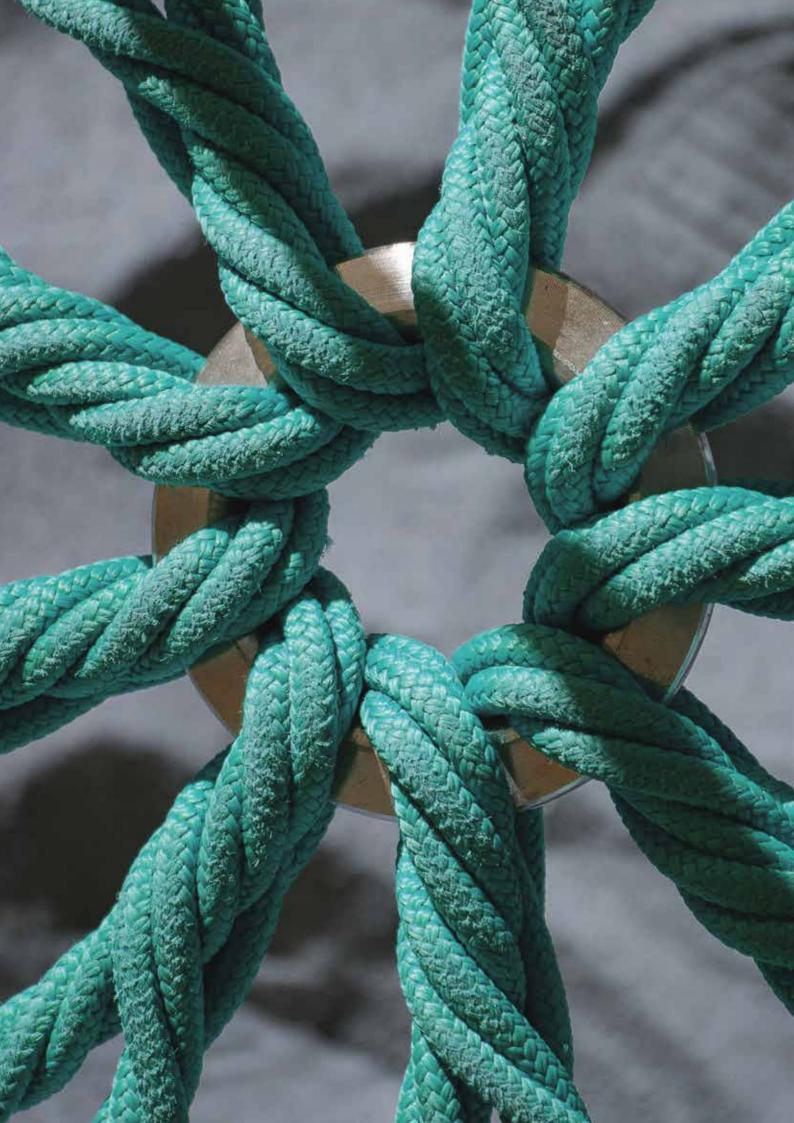
Estimated % of total revenue connected health products and services will represent in the next five years among US and European respondents



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents; N = 281 biopharma respondents in the US; N = 182 biopharma respondents in Europe.

13%

Percent of total revenue, on average, connected health products are projected to represent in five years



Portfolio defense is favored to portfolio expansion

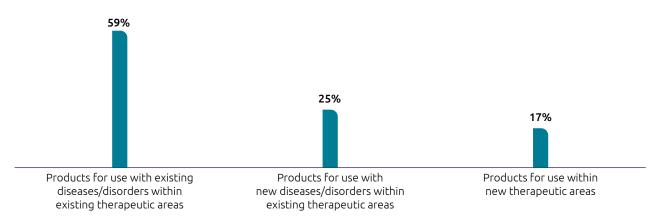
The vast majority (89%) of biopharma respondents said that one of their company's main objectives for its connected health strategy is to develop new products in existing therapeutic areas (i.e., defending their current portfolio). Slightly over half (53%) said a principle objective was to develop new products in new therapeutic areas (i.e., expanding their portfolio to new areas). In addition, we asked respondents for their predictions as to how much of their companies' portfolios would be allocated to connected health in the next five years. On average, respondents anticipate 59% of their portfolios being connected health products for the treatment of existing diseases within current therapeutic areas (see Figure 15).

Organon's Fabio Guarna comments: "Connected health is one way to increase the brand asset of established drugs versus the competitors and it also contributes to improving healthcare through delivering healthcare support and services alongside therapies."

Figure 15

CONNECTED HEALTH WILL BE PREVALENT FOR EXISTING TREATMENT AREAS

Anticipated average allocation of the connected health portfolio in the next five years



Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.

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Connected health portfolios are expected to grow 40 percent

The respondents who said their organization has approved or is testing products have an average of 5.3 digital health products and 5 digital medicines or therapeutics in their portfolios. They expect these numbers to increase by around 40% in the next five years, to 7.5 and 7.1, respectively (see Figure 16). Among those more mature providers, 33% anticipate more than 10 digital health products approved in five years and 19% anticipate more than 10 digital therapeutics. Respondents who are still strategizing their approach to connected health anticipate fewer approved products in five years.

Figure 16

THERE IS A DISPARITY IN ANTICIPATED PRODUCT APPROVALS BETWEEN MATURE AND EMERGING PROVIDERS

Average number of products expected to be approved in market in the next five years*



- Respondents who say their organization has approved products or is testing products
- Respondents who say their organization is strategizing its approach to connected health

Source: Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 439 biopharma respondents from companies who are currently strategizing our approach to connected health; N=84 biopharma respondents from companies who are currently testing/developing connected health product(s) or who have connected health product(s) approved for market. *Range is three to 15 digital health products and three to 11 digital therapeutics among the 84 respondents in the next five years.

FUTURE THERAPEUTIC AREAS FOR CONNECTED HEALTH

We examined the therapeutic areas that biopharma respondents anticipate their company targeting for connected health products in the next five years. Neuroscience-related diseases, such as multiple sclerosis, Alzheimer's, and epilepsy was the top therapeutic area for 45% of respondents. Forty-two percent of biopharma respondents said their company would target rare diseases (e.g., cystic fibrosis, Huntington's disease) with connected health products and services and 40% would target immunology (see Figure 17). A HEOR executive at a global pharmaceutical company believes early detection or even prevention can be a key benefit of connected health in neuroscience: "Connected health is a great opportunity to serve people with seizures. Technology that can see the prodromes [early symptoms] before they happen, through some type of biometry. I feel very excited for these types of innovations that will greatly benefit patients."

Figure 17

NEUROSCIENCE, RARE DISEASE, AND IMMUNOLOGY ARE THE TOP AREAS FOR FUTURE CONNECTED HEALTH PRODUCTS





Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents.



HOW BIOPHARMA COMPANIES CAN CLOSE THE MATURITY GAP AND SCALE THEIR CONNECTED HEALTH PORTFOLIOS

05

This research reveals that most biopharma companies are still developing their capabilities for connected health and that overall maturity of connected health portfolios remains low. Nevertheless, grand ambitions for connected health endure. Given this dynamic, we identify six key actions biopharma companies can take to close the maturity gap of their connected health products and services and scale them effectively (see Figure 18).

Figure 18

SIX KEY ACTIONS FOR BIOPHARMA COMPANIES



Define a commercial connected health strategy aligned to established portfolio plans



Design connected health products to drive measurable value and outcomes



Build a data ecosystem that promotes data sharing and interoperability within, and outside the organization



Upskill talent in data, behavioral science, and agile development



Centralize governance, operating model, and financial structures for connected health to drive growth and regulatory coordination



Build a connected health ecosystem that provides structure and quardrails, but also embraces open innovation

Source: Capgemini Research Institute analysis.

1. Define a commercial connected health strategy aligned to established portfolio plans

Pharmaceutical companies often struggle to deliver commercial connected health products that are strategically aligned with an established portfolio strategy. This research suggests most biopharma companies plan to adopt a "portfolio defense" strategy for connected health, meaning that they are developing new products and services that will complement, supplement, and extend existing offerings within established disease or disorders, as opposed to driving growth in completely new diseases or disorders.

Connected health products and services must be included in a strategic portfolio with an overarching strategy. Biopharma companies can think strategically about such question as, how can we use connected health to bridge long pipeline delays or how can we augment our presence in current therapy areas? In addition, internal investment was cited as a top challenge by a third of all biopharma respondents, including the \$20 billion-plus companies and even those who already have approved products or are testing products. This suggests that funding being earmarked for traditional R&D over novel digital therapeutics can be a hurdle at any stage of maturity. By aligning connected health offerings with established portfolio strategies, biopharma companies will be better positioned to make a clear, compelling case for investing in connected health.

2. Design connected health products to drive measurable value and outcomes

While connected health is perceived as having a potentially very positive effect on value and outcomes, as many as 80% of biopharma companies lack the rigorous process and success metrics to manage the development of connected health offerings.

Based on our experience, the development and launch of a single connected health product can reach costs of \$20–\$40 million. Biopharma organizations need to develop revenue forecasts that outline how and when the business can expect ROI. With clear cost-optimization and revenue forecasts, the connected health enterprise will be regarded as a growth driver, rather than simply another cost center. It will also aid in demonstrating the clinical efficacy of connected health products to healthcare providers and payors and promote reimbursement coverage, which is a top ranked challenge for over a third of biopharma companies.

A director of medical affairs at a global pharmaceutical company elaborates: "Physicians and other healthcare professionals need to have the clinical proof, regardless of the type of product. For example, we have given a digital solution to a physician to use and propose to their patients on a trial basis, and at the end we gathered feedback from the patient and from the physician on their experience and expectations. This evidence helps with approval for certain bodies like the Digital Health Applications [DiGA, Germany's fast-track process implemented in 2019 to get new digital health apps prescribed by doctors]."

3. Build a data ecosystem that promotes data sharing and interoperability within, and outside the organization

Only one-fourth of biopharma respondents said they have applications and standards in place to ensure data interoperability, and a quarter said they have a cloud platform in place to integrate data from different sources, such as electronic medical records from the clinician's office or sensor data from wearables. Less than a third have common frameworks and tools for data collection, analysis, and management of internal and external data. Security vulnerabilities was also cited as the top challenge faced by biopharma companies of any size. Building, delivering, and managing compliant digital products and the data collected by them requires an additional level of infrastructure that is challenging to implement in large biopharma companies. Most data-integration efforts (85% of respondents in our survey) are currently focused on geography and many lack an organization-wide understanding.

Our research on data-sharing masters revealed that faster research and development is a top benefit of engaging in data ecosystems. ¹⁹ A digital health and user experience executive at a US-based multinational biotechnology company advises data ownership within the connected health unit: "Companies need to own the data and have a dedicated team on both the engineering and clinical sides. That is to be sure the data goes from the app to servers and is well organized and secured. In addition, a very strong team of data analysts and data scientists is critical."

Data ecosystems are helping biopharma companies learn from drug discovery and patient experience, so they can bring safer, more effective therapies and solutions to market faster. Mayo Clinic, a US-based provider of integrated healthcare services, education, and research, in 2020 launched a data marketplace called the Clinical Data Analytics platform. The marketplace provides access to anonymized patient data, including disease patterns, diagnosis, treatments, and care plans, to healthcare organizations, providers, and life sciences companies.²⁰

4. Upskill talent in data, behavioral science, and agile development

Our research reveals a gap in many of the skill sets required for connected health. From a technical perspective, augmented and virtual reality, systems thinking and data interoperability, and engineering (e.g., DevOps, algorithms) have the greatest shortage. These technology skills are critical to developing connected health products. Given that the creation of a digital product is often quite different than the traditional process of creating a standalone drug or therapy, biopharma companies need to immerse themselves with skills and talent in areas outside their scientific strengths in chemistry and biology. For example, human-centered design is also a skill in short supply and important in ideating and creating proof of concepts and driving usability.

Moreover, behavorial and social science is critical to understand, and drive behavior modification. This research reveals that only 44% of biopharma business executives said they have a sufficient supply of these skills today (decreasing to 33% among IT respondents). Biopharma companies can use behavioral models to adopt a "realworld" mindset to study patients and provide digital solutions that deliver meaningful outcomes. Omada Health, a US-based "virtual-first," integrated-care provider combines behavioral science and clinical protocols to help people treat and prevent chronic diseases, such as obesity, diabetes, and hypertension.²¹

A digital health and user experience executive at a US-based multinational biotechnology company says human-centered design and behavioral science is key to achieve their goals for connected health: "Our goal is to improve patient care. We need to make sure we meet the specific needs of patients or HCPs. My role is to spend time with both groups to observe, to understand, and to learn about these needs. We are not here to impose solutions; rather, we are here to design solutions that will bring value."

In addition, agile development is a key technology capability for connected health because often, development for a digital product is different than traditional drug development in that the cycle time from concept to product launch is much shorter. Given that technology is ever-rapidly changing, working in an agile and flexible model is critical. Only 21% of biopharma respondents said they employed an agile development model yet approximately 80% believe they have sufficient skills in agile project management. This

dynamic suggests that many biopharma companies might have talent skilled in agile project management; however, their expertise lies in traditional drug development and not in developing software products. Biopharma companies must upskill this existing talent within an agile software model so they can strengthen the broader agile development capability for connected health.

5. Centralize governance, operating model, and financial structures for connected health to drive growth and regulatory coordination

This research reveals that the majority of biopharma companies lack a centralized management and funding arm. Most companies still tap into legacy groups (e.g., traditional R&D, IT) for ideation and identification of new digital innovations, and do not fund connected health business units centrally. Granting autonomy in capability-building and decision making to the connected health unit is critical to effective acceleration and scaling. It will allow the connected health team to work faster, in a more agile manner, and more collaboratively across the organization.

Milena Saleh of Sanofi agrees: "Having a semi-autonomous, autonomous, or separate digital health entity with a different management and engagement model, delegation of authority, and processes, is critical. In this setup, the digital unit is able to be much faster in decision making than what has historically been the case in pharma."

A centrally managed connected health enterprise will also drive transparency in the regulatory process. The regulatory approval process was cited as a top challenge especially among smaller and mid-sized biopharma companies. Given that larger companies in our survey are more likely to have approved connected health products or are testing products, they are less likely to cite regulations as a top barrier, suggesting once a company goes through the process, it knows what to expect. Different types of connected heath products have differing regulatory requirements. For example, for more complex digital therapeutics or SaMD products, the regulatory burden is generally higher in the US and Europe than for a low-risk, companion app. Understanding the specific classification and requirements to obtain regulatory approval in the initial strategy and planning phase for the connected health product is critical to execute regulated development with speed.

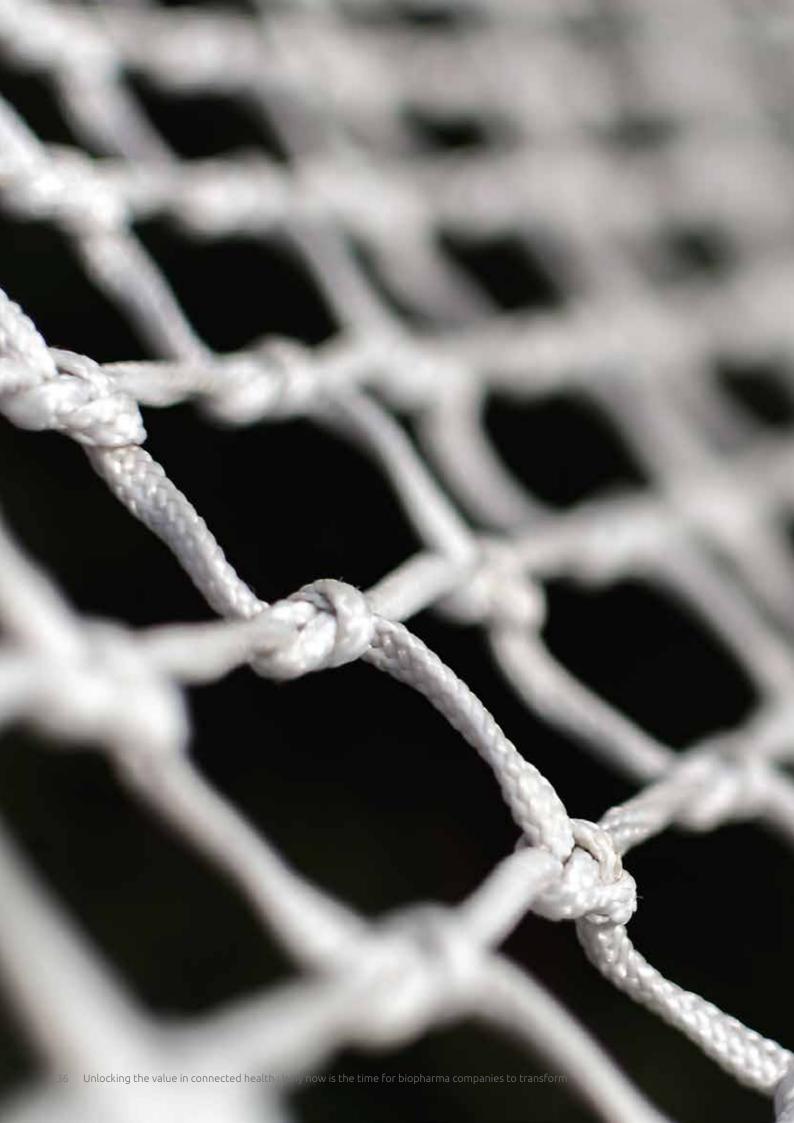
6. Build a connected health ecosystem that provides structure and guardrails, but also embraces open innovation

Biopharma companies need to recognize their capability gaps and then identify and integrate new technologies, tools, vendors, and partners into the ecosystem to fill them. There is no one-size-fits-all approach; rather, an open innovation ecosystem must be created, based on the strengths and needs of the individual biopharma company. It is important for biopharma organizations to look for a broad set of ecosystem partners. Different types of organizations – from technology providers, design and strategy firms to HCPs, payers, policymakers, and academia – will bring unique perspectives and expertise to the ecosystem. A diversified set of partners will help to fill talent needs, expand areas of focus beyond traditional treatment, and also drive cross-industry innovation. Different areas of expertise are important for the ecosystem too. A director of medical affairs at a global pharmaceutical company says: "It is very important to have the different expertise in the same room – medical, marketing, patient services, technology, development, regulatory. We work together toward the same goals and can be much quicker in our decision making and time to market."

There might be a specific skill or area of expertise in which a partner is required, such as AI, as a HEOR executive at a global pharmaceutical company explains: "Smaller and midsize companies, especially, are going to be looking to vendors who are specialized in connected health areas. I think that AI integration into connected health will greatly help the triage management of patients. I think we are going to see a new era in patient intake, and how patients are handled thereafter."

Some biopharma companies might take a different approach, based on the product at hand. For example, the digital health unit at Sanofi has various modus operandi, with some products developed entirely internally and some entirely externally. It connects to solutions of other companies and looks at potential partnerships. Sanofi's Milena Saleh observes: "It is very flexible and that has an advantage, because you are getting the best of what is available. The challenge is that it increases the complexity. So, you must be very clear on the strategy for each product."

Biopharma companies can also create their own internal accelerators for open innovation in connected health. German pharmaceutical company Bayer's digital health accelerator G4A partners with and invests in healthcare startups and technology companies that are developing innovative solutions. Its mission is to scale digital health to create impact, empower lives, and change the healthcare experience. Since launching in 2013, Bayer G4A has supported over 150 digital health companies, resulting in more than 30 collaborations.²² In 2016, Servier launched an e-health division, WeHealthTM Digital Medicine, dedicated to improving the lives of patients and HCPs through digital technology. WeHealthTM also identifies promising startups in digital health with which to co-develop solutions in the company's therapeutic areas.²³

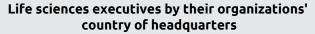


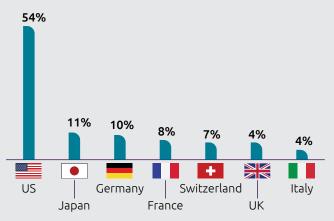
CONCLUSION

The results of this research reveal that many biopharma companies are still developing their strategy for connected health and that capabilities are very much emerging. The field of connected health is established with recognized potential, and many companies have made advancements in building their connected health portfolios and realizing financial and clinical value from them. The question remains, however, as to whether we are anywhere near the tipping point when new technologies will drive lasting change in how we deliver and organize healthcare. With the COVID-19 pandemic accelerating demand for and supply of connected health products and services, biopharma companies are now in prime position to transform and scale their connected health portfolios.

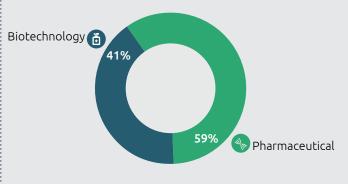
Research methodology

We surveyed 523 executives, manager-level and above (representing 166 companies) from life sciences organizations in the pharmaceutical and biotechnology sectors across seven countries in North America, Europe, and Asia. Respondents must have indicated that their company is currently strategizing its approach to connected health; currently testing/developing connected health product(s); and/or currently have connected health product(s) approved and in market. The global survey took place in October and November 2021. In addition, we conducted in-depth interviews with 10 senior executives at leading global biopharma companies.

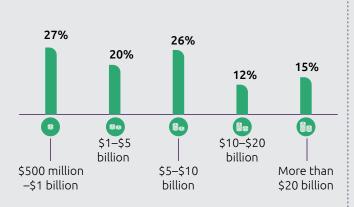




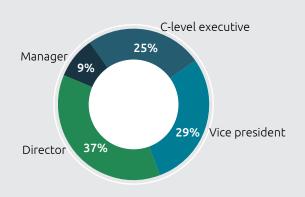
Life sciences executives by their organizations' sector



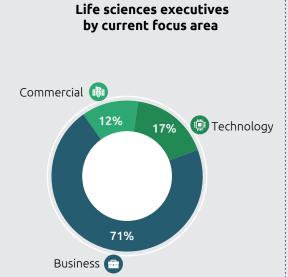
Life sciences organizations by enterprise-level revenue in US\$



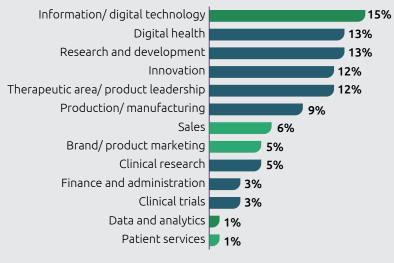
Life sciences executives by current job title



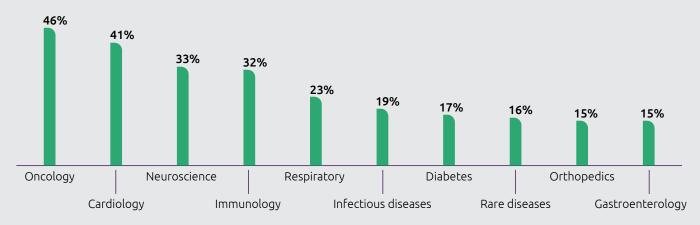
Source: Capgemini Research Institute, connected health survey, October–November 2021, N = 523 biopharma respondents. *The study findings reflect the views of the people who responded to our online questionnaire for this research and are aimed at providing directional guidance. Please refer to the methodology for details of respondents and contact a Capgemini expert to understand specific implications.



Life sciences executives by current department/function across Business, Technology, and Commercial



Top 10 therapeutic areas among life sciences executives' organizations



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About the Capgemini Research Institute

The Capgemini Research Institute is Capgemini's in-house think tank on all things digital. The Institute publishes research on the impact of digital technologies on large traditional businesses. The team draws on the worldwide network of Capgemini experts and works closely with academic and technology partners. The Institute has dedicated research centers in India, Singapore, the UK, and the US. It was recently ranked number one in the world by independent analysts for the quality of its research. Visit us at www.capgemini.com/researchinstitute/

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Embracing digitization for a people-centric future with connected health

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- Our strategic consulting expertise helps organizations create a common strategy that will break through organizational silos and connect functions to facilitate integrated Connected Health design and delivery and drive outcomes across the business.
- Our business transformation capabilities help organizations establish and optimize efficient digital product development and operations based on sound manufacturing processes and digital core best practices.
- We leverage our extensive and robust network to help clients engage with the partners, alliances and early-stage innovators that can help organizations fill capability gaps and thrive in today's digital world.

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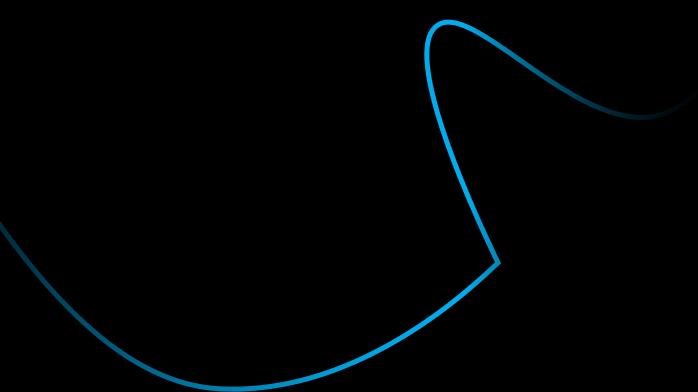


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