The connected health revolution



#GetTheFutureYouWant

In this report, which builds upon our 2022 research, we present our latest assessment of the maturity and adoption of connected health within the biotechnology and pharmaceutical (biopharma) industry. Additionally, we gauge the current level of adoption and maturity among MedTech organizations.

What is the industry's position on connected health?

A large majority of life sciences organizations (63%) report having connected health products already on the market or under development. Moreover, there has been a significant increase in the perceived maturity of connected health enterprises, with around half of life sciences organizations indicating maturity in their approach.

As connected health gains momentum as a segment, with increased adoption and more sophisticated offerings, revenues are also expected to rise. Regardless of the phase of development they are currently in, life sciences organizations anticipate connected health contributing an average of 22% to their total revenue by 2028, underscoring the preference given to connected health initiatives. Furthermore, the convergence of healthcare and technology empowers organizations to implement service-based business models that secure recurring revenue streams.



report having connected health products already on the market or under development.

Executive Summary

How did biopharma progress?

Within the biopharma industry, nearly 20% of organizations have now rolled out connected health offerings – a striking increase from a mere 3% in 2021. While preventive care and wellness remain top priorities for a majority of biopharma organizations, there is a growing emphasis on previously underserved areas, including diagnosis and monitoring. In terms of therapeutic areas, oncology, immunology, and cardiology are primary focuses for most biopharma companies, with emerging areas such as mental health, diabetes, obesity, and dermatology also showing huge growth since 2021. Despite ongoing challenges in collaboration and internal integration, there have been substantial improvements in digital and technological capabilities. An increasing number of biopharma organizations are adopting innovative approaches to product development, as well as forging strategic partnerships to facilitate progress.

Where does MedTech stand?

Within the MedTech industry, nearly 40% of organizations have successfully commercialized connected health products. MedTech companies predominantly focus on digital health solutions such as telemedicine platforms, clinical decisionsupport systems, and wearable technologies. External partnerships play a pivotal role in driving innovation within this industry. Nevertheless, there remains room for improvement in digital, tech, and collaborative capabilities. Currently, fewer than one in two MedTech organizations possess the requisite capabilities to support connected health, highlighting areas for further enhancement and investment. **Executive Summary**

Less than one in two organizations possess the requisite capabilities to support connected health.

What are the preferred connected health solutions across the industry?

Across the life sciences industry, mobile apps, smart medication adherence monitors and apps – which aim to ensure patients stick to correct dosages and course lengths – are the most widely deployed solutions because they address immediate healthcare needs. Additionally, the integration of generative AI technologies holds immense promise, enhancing patient support, personalized care, and operational efficiency.



How can the industry deliver a successful connected health portfolio?

When compared with 2021, we found that biopharma organizations are making progress in strengthening their digital capabilities (such as AI, cloud). However, the life sciences industry continues to face a number of challenges across strategy, governance, funding, technology integration, data management, regulations, and talent that hinder the development of a successful connected health portfolio. To harness the full potential of connected health and drive positive business and patient outcomes, we propose seven practical recommendations:

- Define and articulate your vision and value proposition for connected health
- Design digital product offerings that deliver the proposed value
- Design/develop scalable, secure, and compliant data infrastructure and operations
- Enhance capabilities in digital, engineering, and human-centric design
- Engage with partners, alliances, and early-stage innovators to share expertise and capabilities
- Take measures to bridge the talent gap
- Establish robust quality assurance processes to ensure regulatory compliance.

Who should read this report and why?

Who?

This report is written for C-suite executives from biopharma and MedTech industries and for leaders across connected health functions, including therapeutic area/product leadership, information/digital technology, digital health, clinical research, data and analytics, patient services, clinical trials, innovation, R&D. Its insights will also be of interest to life sciences executives and business leaders from general management, strategy, product, and data and analytics.

Why?

The report delves into the life sciences industry's perspective on connected health. We explore the focus areas for industry executives, examine a range of connected health solutions, and provide actionable recommendations for developing a connected health portfolio.

This report is based on:

- the findings of a comprehensive industry survey of 420 senior executives from leading biopharma and MedTech organizations and
- in-depth interviews with industry executives and

All the organizations surveyed have annual revenues over \$500 million and nearly 70% of them have revenues over \$1 billion.

See the Research Methodology at the end of the report for more details on the organizations surveyed.



Capgemini Research Institute 2024

In an era defined by technological innovation, connected health has emerged as a transformative force within the healthcare sector. While the COVID-19 pandemic acted as a catalyst for the integration of digital technologies in healthcare, recent advances are further accelerating the adoption of connected health. These new offerings, such as smart medication adherence apps, connected rehabilitation tools, clinical decision support tools, on the market afford organizations the opportunity to improve patient outcomes; tap into data-driven, AI-powered clinical insights; and develop new products or enhance existing ones. As these possibilities become apparent to the public, consumer demand for connected health solutions is increasing rapidly.

Our recent consumer research reveals that one in three consumers already owns a health wearable, and 29% are likely to purchase one in the next 12 months.¹ The global connected health market is projected to grow at a compound annual growth rate (CAGR) of 25%, reaching around \$520 billion by 2032 from \$58.2 billion in 2022.² The current research serves as an update to our 2022 connected health report, <u>Unlocking the value in connected</u> <u>health</u>, which assessed the maturity and adoption levels of connected health and explores how biotechnology and biopharmaceutical (biopharma) organizations can manage and grow their connected health portfolios more effectively. In our 2022 research, we discovered that most biopharma organizations were in the early stages of developing connected health models, and the overall maturity of connected health portfolios remained low. We concluded that a majority of organizations lack a rigorous process, success metrics, centralized governance, and adequate funding. Also, there was a general lack of a common frameworks, standards, and tools for data handling in relation to connected health offerings.

In this report, we focus on assessing how far biopharma organizations have progressed over the past two years in addressing their shortcomings and narrowing the maturity gap within their connected health portfolios. We assess how successful they have been in scaling their connected health initiatives and how they have dealt with new challenges. We also trace notable shifts in connected health strategies and initiatives since 2022.

We further broaden our scope to examine the approach of MedTech organizations to connected health, including how they have harnessed AI, cloud, and their attitudes towards collaboration with the wider health ecosystem.

To address these questions and the overarching themes to which they relate, we conducted a global research study spanning large biotech, pharma, and MedTech organizations across nine countries: France, Germany, India, Italy, Japan, Spain, Switzerland, the UK, and the US. The research structure includes a survey of 420 respondents from organizations with annual revenue exceeding \$500 million and in-depth discussions with industry experts. For more details on the survey sample, please refer to the research methodology.

The report comprises five sections:

Life sciences is betting on connected health **O22** Biopharma organizations intensify focus on connected health

Connected health is a top priority for a large majority of MedTech organizations

Implementation of connected health solutions is on the rise 05 Recommendations for building a connected health portfolio.

Defining connected health

Figure 1.

The definition of connected health



We define connected health as the value delivered at the intersection of digital and care. Consumer health services and programs range from digital wellness and fitness to non-regulated digital companions spanning health apps to wearables and coaching tools. Biopharma connected health solutions focus on driving value and outcomes from R&D, developing tools to improve drug asset development and supporting clinical trials to companion apps, regulated digital therapeutics (DTx) and Software as a Medical Device (SaMD) products and device/pill+ connected assets. Connected health in MedTech encompasses a robust suite of offerings ranging from implantable and handheld devices to capital medical equipment and the digital and data ecosystems that surround them and power everything from diagnostics to remote care, procedures, and postprocedure care.



The connected health revolution

Figure 2.

Prevention	Diagnosis	Treatment	Monitoring and follow-up
 Epicore Biosystems' Connected Hydration sweat patch and mobile app Monitors sweat fluid and electrolyte losses, skin temperature and movement Measures hydration, nutrition, stress, and health-related biomarkers 	 Roche's uPath HER2 (4B5) image analysis, Breast An adjunctive computer-assisted digital pathology solution Assesses breast tissue slide images for presence of tumor cells Offers results faster for user-defined regions of interest with whole slide analysis (WSA) and automated pre-com- puting of the slide image prior to pathologist assessment 	 NightWare to treat sleep disturbances Prescription digital therapeutic for temporary reduction of sleep disturbance related to nightmares, caused by Nightmare Disorder or post-traumatic stress disorder(PTSD). FDA cleared Designed to reduce sleep disturbances without waking the patient CSL Behring's B SUPPORT patient app for HEMGENIX® hemophilia B gene therapy Companion app to help patients with hemophilia B transition from factor replacement to gene therapy Guides patients through their treatment journey 	 Abbott's Assert-IQ[™] insertable cardiac monitor (ICM) FDA approved Enables continuous monitoring of patients who recently had a cardiac ablation procedure or who are at risk of developing further arrhythmias such as atrial fibrillation Tracks people experiencing irregular heartbeats over short (three years or more) as well as long term (six years or more)

Continued...

Prevention	Diagnosis	Treatment	Monitoring and follow-up
 Epicore Biosystems' Connected Hydration sweat patch and mobile app Designed for industrial athletes (working in labor-intensive industries such as mining, construction, agriculture, etc.) Alerts users if their fluid loss exceeds 2% of body weight to prevent dehydration and extreme heat exposure 	 Avatar Medical's Virtual Reality patient solution FDA approved Creates 3D representations of patients using their CT and MRI scans within an interactive VR environment in real time Offers clinicians and surgeons accurate insights of their patient's medical images to plan surgical procedures 	 Medtronic's MiniMed[™] 780G system FDA approved and CE marked Automatically adjusts insulin delivery every five minutes based on sugar levels Tracks sugar levels and delivers data to smartphone Allows personalization of glucose target ranges with HCP's aid 	 Zimmer Biomet's WalkAI Tracks recovery by monitoring activities like walking sessions and steps Checks for lower relative gait speed 90 days after hip or knee surgery Generates daily personalized predictions during recovery Notifies the surgeon of any patients using the company's mymobility app who are off-track

Source: Company websites, company press releases, and news articles. *FDA: US Food and Drug Administration; CE: European conformity.



Image: Constant of the second seco

The connected health revolution

About one-quarter of organizations already have connected health products on the market

Our survey of more than 400 biopharma and MedTech organizations indicates a strong appetite for connected health among life sciences organizations. As Figure 3, below, shows, more than 60% of surveyed organizations either already have connected health products on the market or are actively engaged in their development. Only about one-third of organizations are still formulating a strategy. A senior director of digital health at a UK-based multinational biopharma elaborates: *"Beyond driving revenue and improving patient outcomes, connected health is essential for maintaining relevance and competitiveness in our rapidly evolving industry."*

A global product manager at a Swiss healthcare multinational explains how connected care improves accessibility to health for underserved populations: *"We are developing smartphone applications for on-the-go testing, providing clinicians with real-time information, and connecting* with hospital systems to monitor patients outside of the clinical setting. For instance, we have developed smartphone apps to monitor HIV-positive patients in countries in Africa, who may not have access to labs or clinical centers but do have smartphones. This approach allows remote access to diagnostics and ensures seamless data integration with core labs and clinicians."



of surveyed organizations either already have connected health products on the market or are actively engaged in their development.

Figure 3.

One-quarter of life sciences organizations have an approved connected health product

Share of executives who agree with the statements



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 organizations. Notably, larger organizations with annual revenues exceeding \$10 billion are ahead of mid-sized organizations (with annual revenues between \$1 billion and \$10 billion) and small-sized organizations (with annual revenues between \$500 million and \$1 billion). 43% of larger life sciences organizations already have an approved product on the market, compared to 31% of mid-sized companies and only 12% of small-sized companies.

"We anticipate the revenue contribution [from connected health offerings] to rise to 25–30% within the next three years."

Senior director, Digital Health, UK-based Biopharma company

Industry is targeting onefifth of revenue from connected health in five years' time

Our research reveals that life sciences organizations – irrespective of the stage of product development they are in currently – anticipate that connected health will contribute 22% of their total revenue on average. This means the connected health portfolio is expected to grow by 30% in five years underscoring the significant emphasis placed on connected health solutions across organizations. A slightly larger part of this revenue will be contributed by the MedTech industry with an expected 23% contribution from their connected health portfolio compared to the 21% that the biopharma industry will be targeting.

Johnson & Johnson has been increasing MedTech R&D investment and has doubled the value of its product pipeline since 2018. The organization now expects around one-third of its MedTech revenue to come from new products by 2027.³ A senior director of digital health at a UK-based multinational biopharma remarks: *"We presently derive around 7% of our total revenue from connected health offerings. However, with the market experiencing exponential growth, driven by significant advancements in AI, and an evolving regulatory landscape accelerating the development process, we anticipate the revenue contribution to rise to 25–30% within the next three years."*

Figure 4.

Overall, connected health products are expected to account for more than 20% of total life sciences revenue by 2028

Life science industry's revenue from connected health products as a share of total revenue



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 organizations from biopharma and MedTech organizations. * N = 113 respondents from biopharma and MedTech organizations that currently have connected health products on the market. **e stands for expected.

Question asked: Of your organization's total revenue, what is the approximate percentage connected health products represent today? And what is the percentage you estimate they will represent in five years?

Nearly half of organizations believe that their connected health enterprises are mature

About half of the surveyed life sciences organizations report having a mature connected health enterprise. Notably, the percentage of biopharma executives saying this has nearly doubled since 2021. The maturity of connected health portfolios and planning has seen a particularly significant surge, with 52% of biopharma organizations now stating that their approach in this domain has matured, compared with just 26% in 2021. Biopharma organizations have also made substantial progress in their approach to connected health product design and development, with the share of organizations almost doubling compared with 2021. Among MedTech organizations, around two in five have a fully mature connected health enterprise. However, both biopharma and MedTech organizations slightly lag behind the average when it comes to integrating digital operations across the connected health organization. Only around one-third of organizations believe that they have reached maturity in this aspect.

Figure 5.

Integrating digital operations remains a challenge, with only about one-third having achieved maturity in this area

Share of executives that define their organization's connected health enterprise as mature



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 organizations; maturity levels are self-reported by respondents.

Executives from larger organizations consistently report higher maturity of connected health enterprises than executives from smaller organizations do. However, the responses suggest that organizations exhibit comparable levels of sophistication and innovation in product design, irrespective of their size.



of life sciences organizations, with annual revenues exceeding \$10 bn, already have an approved connected health product on the market.

Figure 6.

Executives from larger organizations perceive their connected health enterprise to be more mature than executives from smaller organizations do

Share of executives that define their organization's connected health enterprise as mature, by company size



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 organizations; maturity levels are self-reported by respondents.

Life sciences organizations are now exploring subscription models for both software and devices

As life sciences organizations transition towards value-based care and personalized healthcare solutions. servicebased models are becoming integral to enhancing patient outcomes, improving operational efficiency, and fostering long-term relationships with healthcare consumers. Further, connected health processes support servitization, as organizations can collect data on device usage and performance, allowing them to conduct the necessary monitoring and diagnostics in the field (for example, while working in hospitals or care homes) and also bill their customers based on usage. Today, a guarter of organizations offer subscription-based data services, including medication reminders and analysis of health data. Additionally, over one-third of organizations either currently offer. or intend to offer within the next 12 months, subscription-based wellness apps and services for product purchases, such as diagnostic test kits and medication delivery. Around 25% of MedTech organizations offer connected health devices with usagebased pricing models.

Figure 7.

One-quarter of organizations currently provide subscription-based data services

Share of organizations at each stage of adopting subscription-based models



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 organizations. *N = 168 for MedTech organizations.

24[%]

of MedTech organizations offer connected health devices with usagebased pricing models.

In addition to creating recurring revenue, service-based models generate opportunities for upselling and crossselling, enhancing customer lifetime value. For example, Philips' Enterprise Monitoring as a Service (EMaaS) uses a multi-year subscription model that includes the monitoring software, supported by a dedicated clinical and technical team. This service offers customized ownership levels for monitoring systems (shared or Philips-owned) and financial models (pay-per-use or a mix of upfront costs and subscription).⁴

Sridhar Iyengar, Head of Data and Technology, North America at the Straumann Group, a dental equipment and supplies manufacturer mentions that his vision is to provide Data-as-a-Service and ML-as-a-Service to his stakeholders.⁵ *"It gives a lot of power to our providers in selling their services and at the same time gets more net promoter score (NPS) for us from the patient. All they [the Data and Tech team's internal customers] would have to do is just build their model and run with it."* Commenting on the shift, Dr. Tina Manoharan, former Vice President of Data, AI and Digital Innovation at Philips, states: "In the healthcare sector, adoption of as-a-service models varies depending on factors including reimbursement policies and hospital budgeting. Determining metrics for subscriptions, such as usage or volume, presents complexities. Standardizing subscription models across vendors could simplify matters for hospitals."

She adds: "There's a growing focus on prevention, which challenges traditional business models centered around patient treatment. Collaboration among stakeholders, including industry players, regulatory and reimbursement bodies, will be essential to devising new business models that incentivize patient wellness while ensuring sustainability for healthcare companies."

Ravi Bhardwaj Annamraju, Senior Director of Product Management, Digital Oncology at GE Healthcare, notes: "In traditional fee-for-service models, healthcare providers are incentivized to address immediate concerns, rather than focus on long-term solutions. This often leads to repeated visits and fragmented care, resulting in increased costs and patient dissatisfaction. However, in value-based care models, such as those facilitated by connected health technologies, providers are rewarded for delivering high-quality, comprehensive care that addresses underlying issues and prevents future complications. This shift incentivizes efficient and effective care delivery, ultimately benefiting both patients and healthcare systems."



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Dr. Tina Manoharan Former Vice President of Data, AI and Digital Innovation at Philips



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Ravi Bhardwaj Annamraju Senior Director of Product Management, Digital Oncology at GE Healthcare



Biopharma organizations intensify their focus on connected health

Over half of biopharma organizations have connected health products in development or on the market, a threefold increase since 2021

Biopharma organizations have made strides in the connected health space in the past three years, with the proportion of organizations with approved connected health products on the market increasing from 3% to 19%, a sixfold growth rate. The percentage of organizations developing or testing connected health products also rose substantially, from 13% in 2021 to 35%. So, more than half of organizations have made significant progress in connected health, while the rest (46%) are still developing their strategies. The top drivers of interest in connected health products are providing improved patient support (85%) and gaining deeper clinical insight (83%).

Figure 8.

The number of biopharma organizations with market-ready connected health products surged sixfold since 2021



Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 523 biopharma respondents; March 2024, N = 252 biopharma respondents. *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

Share of executives who agree with the statements

An intensifying focus on diagnosis and monitoring

Looking at different stages of treatment, while diagnosis and monitoring were underserved in 2021, since then, the focus on these areas has clearly improved. Preventive care and wellness remain the top priorities for 62% of biopharma organizations followed by monitoring and follow-up. Research shows that well-designed telerehabilitation (i.e., rehabilitation programs delivered by medical apps) increase adherence to health care providers' (HCPs') recommendations regarding the rehabilitation programs, are safe to use and offer substantial value for health care provider groups.⁶

Figure 9.

Nearly two-thirds of organizations prioritize preventive care

+22% - -62% - +127% - 50% - +25% - 40% - +83% - 32% - 18% -

On which steps in the patient journey does your company's connected health portfolio focus?

Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 523 biopharma respondents; March 2024, N = 252 biopharma respondents. *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

Connected health can also help biopharma organizations in areas such as clinical development and commercial operations. In clinical trials, digital tools improve the patient outreach and participation. Similarly, real-time data connection and remote monitoring are made possible which will allow companies to improve the trial outcomes. Virtual trials reduce the burden for on-site visits and lower the overall costs. Through connected apps that provide targeted doses, therapies, and reminders for medication adherence, commercial operations can also be made more effective.



of biopharma organizations are focusing on preventive care, fitness, and wellness.



Connected health for oncology, immunology, and cardiology are the top priorities for biopharma organizations

Figure 10 indicates how the focus in the use of connected health projects for therapeutic treatment has shifted over these three years. In 2021, for example, two-thirds of the biopharma organizations surveyed had a connected health product for oncology in R&D or already being rolled out, while, today, only half of organizations focus on oncology.

Figure 10.

Mental health and diabetes have become strong areas of focus since 2021

Therapeutic areas biopharma organizations are targeting with connected health products, 2021 vs. 2024



Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 84 biopharma respondents; March 2024, N = 136 biopharma respondents from organizations that currently have approved connected health product(s) at market or are currently testing/developing connected health product(s). *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

Figure 10a zooms in on the seven areas that have gained significant interest, with more than a 100% growth in the focus.



Biopharma industry's increase in focus on connected health for "infectious diseases" between 2021 and now.

Figure 10a.

Therapeutic areas with more than 100% growth rate, 2021 vs. current

Therapeutic areas biopharma organizations are targeting with connected health products, 2021 vs. 2024



Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 84 biopharma respondents; March 2024, N = 136 biopharma respondents from organizations that currently have connected health product(s) approved at market or are currently testing/developing connected health product(s). *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

- **Mental health:** The jump from almost 0% to 17% for connected products could be owing to increased awareness of this topic and isolation experienced during the pandemic. In 2023 the US Department of Health and Human Services (HHS) awarded more than \$64 million in grants to fund mental health services and awareness training.⁷
- Diabetes: Multiple studies have shown that diabetes sufferers are at a higher risk of severe adverse effects of COVID-19 than are non-sufferers. Similar adverse effects were observed as a result of the SARS-CoV and MERS-CoV infections.⁸ Increased hospitalizations could be a key driver of the heightened focus on connected care for diabetes. Eli Lilly and Company's Tempo[®] Personalized Diabetes Management Platform is designed to help type 1 and type 2 diabetes patients to better manage their insulin treatment. This platform can issue reminders to administer medication, provide feedback on bloodglucose levels, and also allow physicians to access patient data and track their progress.⁹
- **Obesity:** Based on research by the World Obesity Federation, the proportion of people with obesity (i.e.,

with a body mass index, BMI \geq 30 kg/m²) is expected to rise to 24% globally in 2035, up from 14% in 2020, while the proportion who are overweight or obese (BMI \geq 25 kg/m²) is expected to reach 51%.¹⁰ This high BMI (BMI \geq 25kg/m²) has an impact on healthcare costs and economic productivity. This economic impact could reduce global GDP by 2.9% by 2035, highlighting the severity of the problem. The U.S. Food and Drug Administration (FDA) has recently approved many new drugs for weight loss.¹¹ These medications require strict adherence to dosage schedules, and digital solutions can improve adherence and overall efficacy.

- **Dermatology:** In 2022, melanoma was the 17th-most common cancer globally.¹² Smart wearables that can track UV exposure and issue reminders to apply sunscreen aid prevention, while telehealth and electronic health records (EHR) can help the patients manage their treatments. The UK's National Health Service (NHS) uses teledermatology technology that allows practitioners to take, store, and share photos and files directly with dermatology specialists, allowing the latter to provide pre-referral advice and quidance.¹³
- Gastroenterology: Gastrointestinal (GI) illnesses include Crohn's disease and gastroesophageal reflux disease and disorders such as irritable bowel syndrome (IBS), constipation, and diarrhea. As the prevalence of GI illnesses increases, demand for endoscopic procedures has risen, albeit slowly.¹⁴ Medtronic's GI Genius[™] uses AI to highlight precancerous lesions with a visual marker in real time, demonstrating a 14% absolute increase in adenoma detection rate compared with colonoscopy alone, for both flat and polyploid lesions.¹⁵



absolute increase in adenoma detection rate realized by Medtronic's GI Genius™ which uses AI to highlight precancerous lesions with a visual marker in real time.¹⁵

- **Orthopedics:** More than 1.7 billion people globally live with musculoskeletal conditions including lower-back pain, neck pain, fractures and other injuries, osteoarthritis, amputation, and rheumatoid arthritis.¹⁶ Lower-back pain is one of the key causes of premature exit from the workforce, adding enormously to the burden on national health services.¹⁷ Telehealth and remote physical therapy can reduce costs for healthcare providers and patients, and can be particularly helpful for lower-income and minority populations.¹⁸
- Infectious diseases: Besides COVID-19, the past few decades have seen the outbreak of a number of new infectious diseases. Since the 1970s, about 40 infectious diseases have been discovered: Ebola, MERS, SARS, Zika virus, avian flu, and chikungunya, to name a few.¹⁹ As the impact of climate change increases, the incidence of such new diseases is expected to rise.²⁰ Telehealth could offer at least part of the solution in how to treat these increased numbers.



Biopharma organizations have improved their digital and technological capabilities to enable their connected health endeavors

Digital and technology capabilities

While still lagging in many of the areas required to strengthen connected health initiatives, we found that the biopharma industry had made considerable progress in artificial intelligence (AI), machine learning (ML) and cloud (see Figure 11). Today, nearly half of organizations focus on AI and ML, while more than 40% have a cloud platform in place. Talking about how AI and ML can accelerate drug discovery, Dr. Anastasia Christianson, former Vice President, R&D Business Technology, Janssen, the pharmaceutical group owned by Johnson & Johnson, says: "[...] ML algorithms help us to predict how other types of cells are likely to react to the same compound(s), giving us a leg up when starting a new study. This AI-based method can be 250 times more efficient than the traditional method of drug discovery."²¹

Spencer Jones, a digital health executive at a global biopharma company, asserts: "AI models allow humans to do what they do, much faster. They can analyze large amounts of data, spot patterns, and provide insights on patient health. In the connected health space, collecting vast amounts of data allows us to take patient-centric actions. With data and AI, we can conduct deep analyses, such as monitoring the circadian cycle's influence on heart rates over time, which would be impossible to track manually for each patient."



of biopharma organizations leverage technologies such as AI and ML to analyze data from their connected health products.

Figure 11.

Biopharma organizations using AI/ML for predictive analysis of real-time data from connected health products has almost doubled since 2021

Digital and technology capabilities



Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 523 biopharma respondents; March 2024, N = 252 biopharma respondents. *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

"AI models allow humans to do what they do, much faster. They can analyze large amounts of data, spot patterns, and provide insights on patient health. In the connected health space, collecting vast amounts of data allows us to take patient-centric actions. With data and AI, we can conduct deep analyses, such as monitoring the circadian cycle's influence on heart rates over time, which would be impossible to track manually for each patient."

Spencer Jones A digital health executive at a global biopharma company

Collaborative capabilities

Nevertheless, the proportion of biopharma organizations focusing on better collaborative capabilities has remained below 40%, similar to 2021. More organizations today are investing in internal collaboration and knowledgesharing alongside dedicated centers of excellence (COE) for connected health.



Figure 12.

The proportion of biopharma organizations with dedicated centers of excellence has surged by 33%

Collaborative capabilities



Source: Capgemini Research Institute, Connected Health Survey, November 2021, N = 523 biopharma respondents; March 2024, N = 252 biopharma respondents. *Despite the differences in the number of organizations surveyed in 2021 and 2024, the sample distribution in terms of geography, revenue size, respondents' job roles, and business functions is similar, making the data comparable.

How do biopharma organizations innovate?

More than 70% of biopharma organizations rely on 'open innovation' (i.e., collaborations with external partners and startups), while two-thirds focus on in-house R&D). Over half also depend on strategic partnerships, joint ventures, participation in accelerators and incubators for innovation in connected health. For instance, Novartis partnered with a Copenhagen-based digital health organization to develop a platform for managing chronic conditions.²²

71[%]

of biopharma organizations rely on 'open innovation' (i.e., collaborations with external partners and startups), while nearly two-thirds focus on in-house R&D.

Figure 13.

About two-thirds of biopharma organizations rely on open innovation and in-house R&D to drive innovation for connected health

Different organizational approaches to collaboration and innovation



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 252 biopharma organizations.



Connected health is a top priority for a large majority of MedTech organizations

Connected health is enabling medical device manufacturers to transform into MedTech organizations by leveraging and integrating digital technologies such as the Internet of Medical Things (IoMT), AI into their products and solutions. This allows them to enhance their portfolio while providing better patient outcomes.

The vast majority of MedTech organizations have connected health products in development or already on the market

In our current research, we found that nearly two-fifths (39%) of MedTech organizations have connected health products on the market – a higher percentage than biopharma – while a similar proportion (38%) are actively testing or developing products. Only one-quarter (24%) of MedTech organizations are currently in the strategy phase. A Vice President and General Manager of Connected Health and Data Solutions at a US-based MedTech company explains: *"Many MedTech companies have recognized the need to deliver added value*

beyond conventional settings such as the operating rooms. So, we are integrating technology throughout the care continuum. Expanding this focus to the full ecosystem, where we can collect and analyze pre-operative and post-operative data, will allow us to differentiate and drive growth."

Majority of MedTech organizations cite gaining deeper clinical insights (85%) and to provide improved patient support (85%)

as the main objectives of their connected health strategy. Bert van Meurs, Chief Business Leader of Image Guided Therapy and Precision Diagnosis at Philips, highlighted: *"We* can automate and accelerate routine tasks to generate patientcentric insights from large volumes of data, to help improve productivity and enhance patient outcomes."²³

39[%]

of MedTech organizations have connected health products on the market – a higher percentage than biopharma.



are actively testing or developing products.



of MedTech organizations are currently in the strategy phase.

Figure 14.

Three in four MedTech organizations already have connected health products on the market or in development



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 168 MedTech organizations.

"Many MedTech companies have recognized the need to deliver added value beyond conventional settings such as the operating rooms. So, we are integrating technology throughout the care continuum. Expanding this focus to the full ecosystem, where we can collect and analyze preoperative and post-operative data, will allow us to differentiate and drive growth."

A Vice President and General Manager of Connected Health and Data Solutions at a US-based MedTech company


Digital health solutions and wearables are top priorities for MedTech

Digital health solutions such as telemedicine platforms, clinical decision-support systems, and monitoring devices are the top priorities for the sector, with more than 60% of organizations offering or planning to offer these as a part of their portfolios. Mei Jiang, former Senior Vice President of Global Digital Innovation and Commercialization at Medtronic, comments on the priorities for the MedTech industry: "As care is increasingly leaving hospital and transitioning to home and community, a key objective for many MedTech companies is how we develop remote patient monitoring and telehealth solutions to make it easier for patients to stay connected. While patients go about their daily lives, we aim to transform the way patients are assessed, monitored, and treated to make it more convenient for them. This provides doctors with better insights and, together, we can deliver better quality of care and outcomes for the patients. Ultimately, we will democratize care for a much wider demographic, the everyday consumers. bevond tools and patients."

Implantables and surgical devices are also a major element. Philip Adamson, M.D., Abbott's Divisional Vice President and Chief Medical Officer, elaborates on how connected implantables can improve quality of life: *"The safety and assurance patients experience when they're monitored in an implantable sensor situation is remarkable. Patients know that their systems are being carefully monitored. They feel safe, that locus of control comes back, and the burden of depression begins to lift." 24*

More than



of MedTech organizations currently offer or plan to offer digital health solutions.



"As care is increasingly leaving hospital and transitioning to home and community, a key objective for many MedTech companies is how we develop remote patient monitoring and telehealth solutions to make it easier for patients to stay connected. While patients go about their daily lives, we aim to transform the way patients are assessed, monitored, and treated to make it more convenient for them. This provides doctors with better insights and, together, we can deliver better quality of care and outcomes for the patients. Ultimately, we will democratize care for a much wider demographic, the everyday consumers, beyond tools and patients."

Mei Jiang

Former Senior Vice President of Global Digital Innovation and Commercialization at Medtronic



"The safety and assurance patients experience when they're monitored in an implantable sensor situation is remarkable. Patients know that their systems are being carefully monitored. They feel safe, that locus of control comes back, and the burden of depression begins to lift."²⁴

Philip Adamson

M.D., Abbott's Divisional Vice President and Chief Medical Officer

Figure 15.

Most MedTech organizations prioritize monitoring devices, digital health solutions, and therapeutic devices in their portfolios

Types of connected health products MedTech organizations currently offer or plan to offer



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 65 MedTech organizations that currently have connected health products in the market and N = 63 MedTech organizations that are currently testing/developing connected health products

Less than half of MedTech organizations possess the digital and technology capabilities required for connected health

Digital and technology capabilities

A connected health product must pass through a number of stages: from strategy and roadmap to research, design and development, regulatory review, commercial rollout, and post-launch operations including monitoring and support. To do so successfully, organizations must build a set of capabilities. In our research, we found that one in two MedTech organizations are harnessing Al/ML to analyze data from their connected health products, while a similar number are focusing on a cloud platform for data integration. However, only a minority are also able to build strong datamanagement capabilities (38%), or user-centric design (34%), as shown in Figure 16. Peter Schulam, Chief Scientific Officer at Johnson & Johnson Medical Device Companies (JJMDC), emphasizes the need for a unified platform: "Our instruments, which before were purely mechanical, can now generate data. We have to think about how we're going to aggregate and process that data and, through this collaboration, we're ensuring it's on a unified cloud platform. This will enable physicians and surgeons to gain insights, with the potential to increase consistency and improve the standard of care."²⁵

Figure 16.

Less than half of MedTech organizations possess the digital and technology capabilities required for connected health

Digital and technology capabilities



"Our instruments, which before were purely mechanical, can now generate data. We have to think about how we're going to aggregate and process that data and, through this collaboration, we're ensuring it's on a unified cloud platform. This will enable physicians and surgeons to gain insights, with the potential to increase consistency and improve the standard of care." ²⁵

Peter Schulam

Chief Scientific Officer, Johnson & Johnson Medical Device Companies (JJMDC)

Collaborative capabilities

Collaboration is another area where MedTech organizations need to make strong inroads. Our research shows that less than 40% of organizations have frameworks that allow knowledge sharing across the organization or external partnerships to drive their connected health initiatives. Similarly, only 31% of organizations have a center of excellence (COE) to drive innovation.



of organizations have applications and standards in place to ensure interoperability of data.

Figure 17.

Many MedTech organizations still lack collaborative capabilities

Collaborative capabilities



How do MedTech organizations innovate?

We found that, for driving innovation in connected health, MedTech organizations primarily prioritize external collaboration, including open innovation, strategic partnerships, and joint ventures. Over half (55%) also invest in in-house R&D to advance their capabilities, while a small group of organizations opt for accelerators and incubators (39%) or acquisitions of startups (29%).



of MedTech organizations rely on open innovation for driving innovation while 59% invest in strategic partnerships and joint ventures.

Figure 18.

MedTech organizations primarily rely on external collaboration and partnerships to drive progress in connected health

MedTech organizations' approach to collaboration and innovation



Both acquisitions and joint ventures help organizations to access required capabilities and expand to new markets and geographies. In 2021, Baxter acquired Hillrom in a multi-billion-dollar deal that allowed Hillrom to expand its portfolio on a global scale and both organizations to catalyze their digital transformations.²⁶ Similarly, to reshape its digital patient outreach efforts, Stryker acquired Vocera Communications, a care coordinator offering smartphone apps and workflow analytics software, as well as its own handheld communications hardware for hospital staff.²⁷



Implementation of connected health solutions is on the rise

We found that a number of organizations have been able to scale selected connected health tools. The decision of which to scale could be influenced by factors such as business value generated; ease of obtaining regulatory approval; the availability of tools and capabilities to facilitate scaling; the required level of investment; and availability of quality data, among others.

About one in five organizations has already commercialized mobile apps (for patients to capture and track symptoms at home) and smart-medication adherence tools or apps – or currently have such products undergoing regulatory review. Unlike more complex medical devices, engineers can develop and deploy mobile apps quickly, often within a few months or even weeks. Widespread accessibility via smartphones ensures broad adoption. Furthermore, their versatility allows continuous updates and customization, enabling organizations to adapt quickly to changing market demands and patient needs.

Abbott's NeuroSphere Virtual Clinic is a connected health neuromodulation product for patients living with chronic pain or movement disorders, such as Parkinson's disease. It is a secure, in-app video chat and remote programming tool, accessible by patients via an app on a mobile device. This platform enables remote office visits, during which physicians can assess progress and modify electro-stimulus treatment in real time, in the same way as in an in-person appointment. Physicians can also evaluate treatment outcomes and make further adjustments using the device.²⁸

Ryan Lakin, Divisional Vice President of Digital Solutions at Abbott Medical Devices, comments: *"The advantage of working off smartphones is they get smarter. They develop better cameras, voice tools and faster processers, giving them everstronger capabilities."²⁹ Professor Chun Wang, Head of the School of Mechanical and Manufacturing Engineering and Director of the ARC Research Hub for Connected Sensors for Health at UNSW Sydney, says: <i>"Connected health sensors are emerging as a transformational technology to address a wide range of pressing issues, such as remote health management of chronic diseases for at-risk populations; rehabilitation and chronic disease management of frail and older people; monitoring acute pain and blood-lactate level in athletes; and smart rehabilitation and treatment of neurological diseases."³⁰*

Connect America Home[™], a digital health and safety platform, provides secure continuous monitoring and emergency and non-emergency support for aging and vulnerable populations. This platform integrates remote patient monitoring (RPM), and medication management, alongside tech-enabled services such as AI-enabled virtual assistance and support for social determinants of health (SDOH) needs.³¹ Samsung Electronics' smartwatch and associated mobile app that detects signs of sleep apnea has obtained De Novo authorization from FDA.³² Samsung's latest wearable, the Galaxy Ring, includes health-tracking features such as heart rate and sleep monitoring. Hon Pak, Head of the Digital Health Team at Samsung Electronics, explains: *"The ring, which is fitted with sensors, will be able to give readings on heart rate, respiratory rate, movement during sleep, and the time it takes a person to fall asleep once in bed. The ring will be able to give a vitality score that collates data about physical and mental readiness, indicating the productivity level of the patient."* Additionally, Samsung is researching non-invasive glucose monitoring and blood-pressure sensing⁻³³

BMJ Best Practice, a clinical decision-support tool, offers step-by-step guidance on prevention, diagnosis, and treatment, customized for patient consultations. It provides advice on symptom evaluation, recommended tests, and treatment approaches. Health Education England (HEE), an executive non-departmental public body of the Department of Health and Social Care, extends access to the tool to all NHS staff in England.³⁴ "Connected health sensors are emerging as a transformational technology to address a wide range of pressing issues, such as remote health management of chronic diseases for at-risk populations; rehabilitation and chronic disease management of frail and older people; monitoring acute pain and blood-lactate level in athletes; and smart rehabilitation and treatment of neurological diseases."³⁰

Professor Chun Wang, Head of the School of Mechanical and Manufacturing Engineering and Director of the ARC Research Hub for Connected Sensors for Health at UNSW Sydney

Figure 19.

One in ten life sciences organizations has already commercialized health-tracking apps, smart-medication adherence tools, and smart home healthcare devices



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 biopharma and MedTech organizations. *ePRO devices: Electronic patient-reported outcome devices.

Generative AI for connected health and healthcare

Generative AI has a number of applications in connected health as well as in healthcare. Organizations are already using generative AI models to produce synthetic data, analyze existing data, automate documentation and reporting, manage suppliers, design products, and identify sites for clinical trials.

Using Google Cloud's latest Vertex AI and generative AI technologies, Apollo Hospitals has developed a new Clinical Intelligence Engine (CIE), designed to provide secure and reliable healthcare services across India. Utilizing Google Cloud's large language models (LLMs) and the vast dataset collected by Apollo Hospitals, CIE offers proprietary solutions to assist doctors in quickly determining the best course of action for patients. Additionally, Apollo Hospitals intends to utilize the more advanced Med-Pathways Language Model (Med-PaLM) 2, a Google-developed LLM trained on medical



knowledge. This model can answer medical enquiries and generate authentic summaries of clinical text.³⁵

RhythmX AI, an AI-native healthcare organization, has developed a precision-care platform to assist doctors in delivering hyper-personalized care. Using generative and predictive AI algorithms, the system offers actions and recommendations tailored to the individual patient. Doctors can use a natural language interface as an AI co-pilot during patient appointments as brief as 10 minutes.³⁶

Moderna, a biopharma organization, has announced its ongoing collaboration with OpenAI to integrate generative AI into its operations responsibly. Their partnership began in early 2023, with the launch of Moderna's instance of ChatGPT, mChat, built on OpenAI's API.

Since its debut, Moderna has deployed over 750 GPTs across its organization. Among these is the Dose ID GPT, which utilizes ChatGPT Enterprise's advanced data analytics feature to assess the optimal vaccine dose set by the clinical study team. Dose ID provides a rationale, references sources, and generates informative charts, facilitating detailed human-led reviews. This process prioritizes safety and optimizes the vaccine dose profile for late-stage clinical trials.³⁷

Google Research and Fitbit are developing a Personal Health LLM designed to provide users with enhanced insights and recommendations within the Fitbit mobile app. This model will offer personalized coaching to assist Fitbit users in reaching their fitness and health objectives. For example, the LLM could examine variations in sleep patterns and propose adjustments to workout intensity to enhance sleep quality.³⁸

Figure 20.

Three in five organizations are currently developing a roadmap for integrating generative AI

Major areas of focus to build generative AI capabilities



Figure 21.

Generative AI can add value throughout the healthcare value chain, including in connected health

Research

Data: Synthetic data generation tailored to patient demographics and health conditions

Design: Generative product design with optimized form factors, virtual prototyping

Research operations: Automated documentation and literature review

Operations

Manufacturing: Gen AI augmented manufacturing, predictive maintenance for connected devices to minimize downtime, user manuals for operators

Supply chain: Supplier management, inventory optimization, demand forecasting

Quality control: Automated inspection, documentation and reporting

Sustainability: Resource optimization and conservation

Product development journey

Clinical development

Design: Identifying sites for clinical trial

Operations: Automated real-time data collection and analysis

Execution: AI-powered digital companions

Submission: Automated clinical trial reporting using real-world evidence

Regulation and compliance

Regulatory/pharmacovigilance: Al-powered adverse event detection systems for continuous monitoring Medical affairs: Data aggregation and analysis tools for generating insights from real-world patient data

Regulatory affairs: Al-powered regulatory review systems for ensuring compliance with healthcare regulations

Labeling: Automated label generation based on product specifications and regulatory requirements

Regulatory submissions: Al-powered tools for electronic common technical document (eCTD) preparation/submission

Commercialization and launch

Patient support services: Gen Al-powered patient assistance providing 24/7 support

Patient/HCP interactions: Telemedicine platforms enabling remote consultations and monitoring

Treatment management/post-procedure care: Mobile apps/tools for medication adherence and remote follow-up care after procedures

Post-launch

Post-launch surveillance: GenAI-powered monitoring of connected device performance to minimize device downtimes

User engagement and feedback analysis: GenAl tools gather and analyze user feedback based on engagement and behavioral patterns to identify areas for improvement and innovation (for example, feature enhancement, user-centric design upgrades areas for improvement and innovation (for example, feature enhancement, user-centric design upgrade

Incident reporting: Automated generation and submission of reports in case of any incidents or adverse events

Source: Capgemini Research Institute analysis.

Figure 22.

Over half of organizations are currently piloting generative AI for interactions with patients and HCPs



Areas in which organizations are currently embedding generative AI for connected health products and services

*Percentages represent share of organizations at each stage of generative AI implementation for connected health products and services. Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 biopharma and MedTech organizations.





Recommendations for building a connected health portfolio

While life sciences organizations have made considerable progress in building connected health portfolios, there remain challenges to be overcome. Our previous research laid out six specific <u>recommendations for</u> <u>biopharma organizations</u>, which remain valid today. In this report, based on the current state of connected health adoption and enterprise maturity, we offer additional recommendations and actions for developing and scaling a connected health portfolio.

Figure 23.

Recommendations for developing and scaling a connected health portfolio



Source: Capgemini Research Institute analysis.

Define and articulate your vision and value proposition for connected health

The first step towards building a connected health portfolio is devising a robust strategy and roadmap.

Organizations must have a clear idea of which therapeutic area or connected solutions they should be prioritizing and the value, the patient outcome, that they would like to deliver. As figure 10a shows, therapeutic areas such as mental health and diabetes are gaining momentum. Biopharma companies must determine the right therapeutic area that is gaining traction in the market while also aligning with their business strategy.

They must then identify the right solutions to apply to each focus area, depending on their current levels of maturity in terms of data, technological and collaborative capabilities. Once they have gathered all the informative data, they must back those investments with the clearest business cases.

Amir Zur, the former Executive Director and the former Head of R&D of Digital Health Products at Takeda, highlights the importance of quantifying value: *"When considering whether to proceed with a particular use case, we prioritize solving unmet* patient needs. By quantifying the impact of the effort required to do so, on both the organization and the patient, we can prioritize and strategize effectively. This approach ensures that our decisions are data-driven and aligned with our overarching goals."

If organizations are still in the early stages of building internal and external capabilities for connected health, they could opt for low-risk, high-benefit use cases and implement them on a small scale to explore potential return on investment (ROI) on a larger scale with minimum risk, as well as gauging potential business outcomes.

A senior director of innovation at a European multinational pharmaceutical organization explains how they determine the success of a pilot initiative: "We look at the accuracy of data collected through connected devices, [and assess] patient, and healthcare provider (HCP) satisfaction, feedback gathered from HCPs, and, most importantly, adherence to the device in determining the outcome of the pilot."

We also found that mobile health apps and smart-medication adherence tools are the most widely deployed connected health instruments, being relatively simple and capable of swiftly addressing some of the most pressing issues, such as patient adherence and remote monitoring. "We look at the accuracy of data collected through connected devices, [and assess] patient, and healthcare provider (HCP) satisfaction, feedback gathered from HCPs, and, most importantly, adherence to the device in determining the outcome of the pilot."

A senior director of innovation at a European multinational pharmaceutical organization



"When considering whether to proceed with a particular use case, we prioritize solving unmet patient needs. By quantifying the impact of the effort required to do so, on both the organization and the patient, we can prioritize and strategize effectively. This approach ensures that our decisions are datadriven and aligned with our overarching goals."

Amir Zur

Former Executive Director and the former Head of R&D of Digital Health Products at Takeda

Once organizations have made strides in developing their connected health enterprises, they need to **focus on** long-term viability, while selecting which tools to scale. Ravi Bhardwai Annamraiu of GE Healthcare elaborates on the selection process for long-term focus areas: "We generally start by taking a five-year outlook, examining disease pathways and external market data sources such as Centers for Medicare and Medicaid Services (CMS). We then analyze disease progression, tech trends, and regulatory policy updates. We will also consider paver-reimbursement policies. Until recently, solutions such as remote patient monitoring (RPM) and connected care coordination weren't eligible for reimbursement. *However, patient and provider convenience and cost-effectiveness* are the most important factors. RPM. at-home hospital models are gaining traction because they are highly convenient, as well as cost-effective."

Design digital product offerings that deliver the proposed value

While designing connected health offerings, it is crucial to identify and tailor the product or service to specific healthcare and wellness needs. Firstly, organizations should measure usability and effectiveness of the solution. Integrating measurement scales into the design allows precise quantification of outcomes.

Besides tracking patient outcomes, regulatory compliance and risk management are key pillars. However, only half of organizations report highly mature regulatory compliance (48%) and quality management (51%) procedures. A similar proportion of organizations are well-prepared to tackle regulatory compliance complexities concerning cybersecurity, device interoperability and quality control. Rather than conducting quality and regulatory compliance checks at the end of the design process, organizations should integrate simultaneous checks to save time and improve operational efficiencies. This approach not only streamlines regulatory review cycles but also ensures product safety.

Incorporate a 'digital-first' approach into your product strategy

Organizations should continuously refine their offerings by evaluating emerging trends and technologies. This enhances product functionality and facilitates long-term value creation. Implementing a 'digital-first' approach into the product strategy facilitates continuous refinement of products. While Software as Medical Devices (SaMD) are not new to the industry, today organizations also have the opportunity to develop AI/ML-enabled medical devices. These devices help the organizations improve patient outcomes in a number of ways – enhancing diagnostic accuracy, improving operational efficiency, continuous monitoring and alerts to HCPs as and when needed. As of May 2024, FDA has authorized 882 AI/ ML-enabled medical devices in the US.³⁹

A senior director of digital health at a UK-based multinational biopharma organization elaborates on their organizational approach to designing connected product offerings: "*Right from the inception of the project*, we emphasize interdisciplinary collaboration within the oraanization. We also conduct aualitative interviews and quantitative surveys to hear directly from a subset of our end-users. By involving business functions across the value chain. includina desian. enaineerina. medical. reaulatory. and quality, and talking to users, we develop a comprehensive understanding of the concept's feasibility. the product's intended use, regulatory requirements, and user needs. This also minimizes the risk of overlooking compliance issues or designing products that lack real-world utility. These kinds of early intervention set a solid foundation for tackling the complexities of product development and deriving tangible outcomes."

Stephen Gianelis, a pharma executive, elaborates on the return on investment, "As the cost of development is substantial, it takes a considerable amount of time to recover these investments. The opportunities lie in brand recognition and how positively the products are perceived in the market. We focus on continuously enhancing our products' usefulness while continually adding value with the desire to see a positive return on investment" "As the cost of development is substantial, it takes a considerable amount of time to recover these investments. The opportunities lie in brand recognition and how positively the products are perceived in the market. We focus on continuously enhancing our products' usefulness while continually adding value with the desire to see a positive return on investment."

Stephen Gianelis A pharma executive



Identify the digital touch points

To deliver the expected value from the connected products and services, organizations need to understand how the users will interact with the connected health products and services. This will help in improving the design process and also in ensuring that the data on user behavior is collected. Further, this will also allow the organizations to personalize the user experience.

Design and develop scalable, secure, and compliant data infrastructure and operations

Value is derived from data from connected sources through integrating, safeguarding, managing, and analyzing it to generate guiding insights. Organizations, therefore, ought to prioritize investments in data management and governance to enable secure data transactions, integration, and analysis.

We found that more than half of life sciences organizations lack the data capabilities essential to building a connected health portfolio. As Figure 24 shows, only about half of the

surveyed organizations report a significant level of readiness in adhering to data-privacy laws and ensuring security. Less than 50% of the organizations have fully mature capabilities in areas such as data aggregation, designing for data interoperability, and data modeling and analysis. And only about one-third of organizations are equipped to handle unstructured data. This indicates a need for improvement across all aspects to attain higher maturity levels in data operations for connected health.

Less than %

of organizations have fully mature capabilities in areas such as data aggregation, designing for data interoperability, and data modeling and analysis.

Figure 24.

More than half of organizations lack sufficient data capabilities

Share of organizations reporting high maturity levels in various elements of data operations



According to a survey sponsored by Roche Diagnostics, 43% of healthcare sector executives identify disconnected or incompatible systems/data as one of the greatest inhibitors of a data-driven business strategy.⁴⁰ A Patient Safety Consultant at a multinational biopharma company explains his organization's approach to integrating data from various sources: "Our aim is to consolidate all information into a central repository or 'data lake' for reusability, while ensuring compliance with privacy regulations such as GDPR, especially in our external collaborations. However, handling individual-level data presents complexities, and we're continuously navigating this challenge. Additionally, the storage and transfer of data, especially across geographical boundaries, require careful consideration. Collaborating with partners simplifies our data model and enhances the accuracy and usability of the collected data."

Two-thirds of organizations that either have connected health products in development or on the market are using data collected from connected health devices to develop new revenue streams or new innovative products. Over half are using it to improve existing products and offer personalized care. However, only 37% of life sciences organizations have common frameworks and tools for collecting, analyzing, and managing both internal and external data, including patient data, real-world outcomes data, and molecular and clinicaltrials data. Only 45% of executives indicate that their organizations have implemented a cloud platform for seamlessly integrating data from various sources, including EHR patient data, electronic medical records (EMR) data from clinicians' offices, sensor data from wearables, and diagnostic devices. Navify digital solutions from Roche diagnostics, for instance, is an open data ecosystem that securely integrates and consolidates data in one location, accelerating access to information and insights to all stakeholders.⁴¹ Commenting on this solution, a product manager at the organization states: *"Tools like Navify efficiently bridge the [gap between] data coming from, for example, a pathologist, an X-ray center, and a diagnostics center, enabling us to build a complete patient file and swiftly administer the right treatment."*

Life sciences organizations must establish robust data and analytics frameworks to facilitate the aggregation, management, and processing of health-related data from diverse sources. This ensures that data is accessible and reliable, laying the groundwork for the advanced analytics and insights generation essential to enhancing patient care and driving innovation in healthcare delivery.



of organizations have implemented a cloud platform for seamlessly integrating data from various sources.

37[%]

of life sciences organizations have common frameworks and tools for collecting, analyzing, and managing both internal and external data, including patient data, real-world outcomes data, and molecular and clinical-trials data.

Strengthen data governance

A data governance framework that outlines the roles and responsibilities of different parties is essential to maintain the data integrity and ensure compliance to the various data privacy requirements. Data governance also brings in standardization of data across the enterprise allowing for better interoperability. Further, organizations should choose the right operating model for their data (a centralized model or a hub-and-spoke model or a mix) based on their data maturity.

Build a data-driven ecosystem

As the data generated by IoMT rises exponentially and as care becomes increasingly virtual, organizations have an opportunity to collaborate with their peers and share data to improve patient experience and their operational efficiencies. Establishing strong data governance, promoting data literacy and investing in advanced analytics and AI will help in unlocking actionable insights. Further, collaborating with tech firms, startups can fill in the capability gaps. For instance, Mayo Clinic is collaborating with Google Cloud to improve the efficiency of clinical workflows, make it easier for clinicians and researchers to find the information they need using generative AI.⁴²

"Our aim is to consolidate all information into a central repository or 'data lake' for reusability, while ensuring compliance with privacy regulations such as GDPR, especially in our external collaborations. However, handling individual-level data presents complexities, and we're continuously navigating this challenge. Additionally, the storage and transfer of data, especially across geographical boundaries, require careful consideration. Collaborating with partners simplifies our data model and enhances the accuracy and usability of the collected data."

A Patient Safety Consultant at a multinational biopharma company

Enhance capabilities in digital, engineering, and human-centric design

In order to build technically robust, compliant solutions, organizations must incorporate best practices of engineering when designing and developing connected health products. Below, we list a few key areas of focus:

Lifecycle management

As a part of their lifecycle management practices, organizations must monitor their processes continuously, incorporating feedback into future product development. Agile development methodology is an iterative, adaptive approach that organizations should consider adopting. DevOps processes can also help in streamlining the deployment process, improving collaboration between teams and enabling faster delivery of features.

Digital solutions engineering

Organizations operating in the healthcare sector must deal with the unique challenges of complex regulatory overview, stringent data security, and privacy requirements. For instance, three-quarters of executives surveyed mentioned that patients expect transparent communication from providers regarding how their health data feeds into product improvement. Nevertheless, over one-third (34%) of executives admit their organizations' lack of preparedness in addressing data-protection regulations.

Digital solutions must be engineered to navigate these complex requirements. A micro-services architecture can enable scaling, while facilitating seamless integration of services. Similarly, investing in cloud technologies allows organizations to store, process, and analyze large volumes of healthcare data while providing scalability.

Continuous focus on innovation

Advancements in technology open up novel opportunities for life sciences organizations.

- The Virtual Reality (VR) medical solution developed by Avatar Medical[™], a French-US startup, creates interactive 3D representations of patients using their stored medical images. These high-fidelity, lossless (preserving detail and quality) 3D avatars are generated in real time, offering clinicians and surgeons an accurate and immediate understanding of their patients' medical images.⁴³
- Zimmer Biomet Holdings has launched WalkAI, an AI model designed to identify patients at risk of experiencing decreased gait speed 90 days after hip or knee surgery.

Integrated with the mymobility® Care Management Platform, WalkAI utilizes patient gait data collected through mobile phones, which it sends to healthcare professionals via the mymobility clinician dashboard to assist assessment, diagnosis and prognosis.⁴⁴

Platform integration

It is essential to connect the various devices, platforms, and solutions smoothly. Interoperability is a key challenge for many manufacturers. Standards such as Fast Healthcare Interoperability Resources (FHIR), Health Level Seven (HL7) and Digital Imaging and Communications in Medicine (DICOM®) can support integration and interoperability.

Human-centric design

Only one in three (34%) organizations in our research mentioned that they have design systems in place to drive a user-centric development approach in their connected health portfolio. Focusing on a human-centric design helps in enhancing usability and improving engagement. Organizations need to design their products by understanding the pain points of end-users. They also should build feedback loops that can help them iterate and refine the user interface and improve upon the user experience. Ensuring collaboration across design teams, HCPs, end users, and behavioral scientists is an essential part of this process.

34[%]

of organizations have design systems in place to drive a user-centric development approach in their connected health portfolio.

Engage with partners, alliances, and early-stage innovators to fill capability gaps

Collaborating with players across the healthcare ecosystem allow life sciences organizations to access expertise and technologies, as well as resources, which may not be available in-house. This will, in turn, help accelerate innovation. Further, participating in open, collaborative data ecosystems offers access to diverse data sources.

Open innovation is the preferred approach to drive innovation for 71% of the industry. Organizations are collaborating with IT service providers (70%), startups (65%), and also focusing on strategic partnerships and alliances (65%). In March 2024 Johnson & Johnson announced its collaboration with Nvidia to embed AI within devices and platforms from pre-op to post-op stages, to analyze surgical video, automate documentation, and ensure surgeons have access to all relevant data.⁴⁵ Commenting on this partnership, Shan Jegatheeswaran. Vice President and Global Head of Digital, MedTech at Johnson & Johnson MedTech, says: "One of the major challenges in scaling AI for surgery is the closed design of surgical technologies. Bringing advanced edge computing hardware and software to the OR enables scalability of innovation and new AI-powered solutions for clinical decision-makina. education and trainina. and collaboration – with the ultimate goal of advancing patient care."46

"One of the major challenges in scaling AI for surgery is the closed design of surgical technologies. Bringing advanced edge computing hardware and software to the OR enables scalability of innovation and new AI-powered solutions for clinical decisionmaking, education and training, and collaboration – with the ultimate goal of advancing patient care."⁴⁶

Shan Jegatheeswaran

Vice President and Global Head of Digital, MedTech at Johnson & Johnson MedTech

Figure 25.

Seven in ten life sciences organizations collaborate with IT service providers



Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 biopharma and MedTech organizations.

Such collaborations can be successful only when objectives are aligned, and the roles and responsibilities of each player are clearly defined. However, we found that only about onethird of biopharma (29%) and MedTech (35%) organizations have a partnership strategy that defines role, responsibilities, and aligns objectives on connected health with those of their partners.

Moreover, it is important to collaborate closely with governmental bodies and policy institutions to ensure the overall development of the ecosystem. The World Health Organization (WHO) launched the Global Initiative on Digital Health (GIDH), a managed network of organizations, institutions, and government technical agencies that aims to build capacity and co-ordinate efforts to encourage local development, maintenance, and adaptation of digital health technologies.⁴⁷

Further, Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance (IDERHA) is a European public-private partnership (PPP) initiated in April 2023, comprising 33 academic, clinical, MedTech, pharmaceutical, and IT partners, along with patient-advocacy organizations and public authorities. IDERHA is developing one of the first pan-European health-data spaces, with the goal of overcoming barriers related to accessing, integrating,

Capgemini Research Institute 2024

Only about one-third of biopharma (29%) and MedTech (35%)

organizations have a partnership strategy that defines role, responsibilities, and aligns objectives on connected health with those of their partners.

and analyzing health data. As a result, it hopes to harness its full potential to enhance patient care and advance medical research. As part of the Europe Beating Cancer Plan, IDERHA uses health data and technologies such as AI/ML to enhance early detection of lung cancer and subsequent disease management.⁴⁸

Take measures to bridge the talent gap

As do many sectors, healthcare faces a talent shortage that hinders connected health initiatives. Only a minority of organizations mentioned that they had an adequate supply of technical skills such as AR/VR and generative AI. Entrepreneurial and behavioral skills are also in short supply (see Figure 26).

Figure 26.

A shortage of technological and behavioral skills persists among life sciences organizations

We have an adequate supply of this skill/area of expertise available to our connected health enterprise



Two-thirds of organizations prefer to bridge this gap internally through upskilling of the existing workforce, while 56% indicated they would hire new talent. Nearly half prefer partnering with startups. Interestingly, some organizations are turning to AI to help them with the hiring process. For instance, Takeda Pharmaceuticals relies on AI to screen resumés, allowing it to fill positions faster and more efficiently. In addition, the organization is using AI tools to assist in the search for and recruitment of new talent, for example by identifying the number and quality of developers are operating in the areas into which the organization wants to expand.⁴⁹

Figure 27.

The vast majority of organizations are upskilling their workforces to bridge an identified skills gap

Ways in which organizations are bridging the skills gap



Establish robust quality assurance processes to ensure regulatory compliance

Life sciences is one of the most highly regulated industries and for good reason. Regulations are necessary to ensure the safety and well-being of patients. Our research has however found that there are gaps in the preparedness to meet the various regulatory standards.

A software issue in an insulin pump mobile app has led to more than 200 injuries prompting FDA to issue a Class-I recall (reasonable probability of adverse health consequences or death) in the US.⁵⁰

Figure 28.

Organizations preparedness for various regulatory measures falls short

How prepared is your organization to deal with the following areas?



To ensure organizations are compliant with the necessary standards and approvals, a robust quality assurance (QA) framework and adherence to the framework is crucial. The QA framework should outline the standard operating procedures across each step – design, development, testing and operations – and should highlight the required protocols to be followed before launch. Considering the nature of data being collected and analyzed, stringent data privacy and security measures must be implemented alongside regular security audits. Continuous monitoring of devices and solutions post launch will help in ensuring there are no gaps in performance or compliance.

Regulatory compliance is also relevant for legal manufacturers (companies that are legally responsible for design, manufacturing, packaging and labeling of a medical device regardless of whether these operations are carried out by the companies themselves or by third parties). As these companies assume the responsibility for the product, it is important for them to have processes that ensure the product safety, compliance with regulations, and also conduct post-market surveillance to monitor performance. They also must have a system that allows for the traceability of various components used in the device.



Conclusion

The potential of connected healthcare to improve accessibility and quality of life, while also relieving the burden on national health networks, is unquestionable. Consequently, both the biopharma and MedTech industries are focusing on connected health solutions, with the life sciences industry targeting more than one-fifth of its revenue from connected health portfolios within five years. Another interesting, related trend is the emergence of service-oriented business models to cater to the diverse needs of HCPs, patients, and other stakeholders. Although the proportion of biopharma organizations with approved connected health products on the market is less than 20%, this represents a sixfold increase since 2021. MedTech organizations are focusing with even greater intent on the space, with nearly three in four already having connected health products in development or on the market. The challenge for the industry lies in building the technical capabilities required to scale connected health solutions successfully. Further, the advent of generative AI presents exciting new opportunities for the industry to improve patient outcomes. It is imperative that the life sciences industry invest in connected health; define a clear vision; develop offerings that can provide measurable impact; invest in digital, engineering, and a scalable data infrastructure; and strengthen collaborations with other stakeholders in the ecosystem. This will allow organizations to drive value for all stakeholders while revitalizing the healthcare sector overall.

Research methodology

We conducted a targeted survey of 420 industry executives from various biotechnology, pharmaceutical (biopharma), and MedTech organizations that are exploring connected health initiatives and have annual revenues exceeding \$500 million. Of these, 252 organizations belong to the biopharma industry, and 168 to the MedTech segment. They are based in nine countries across North America, Europe, and Asia-Pacific. The global survey took place in March 2024. The distribution of these respondents and their organizations is provided below.

Organizations by country







Organizations by annual revenue




organizations.

Respondents by function

19%

15%

13%

11%

11%

9%

8%

8%

4%

Source: Capgemini Research Institute, Connected Health Survey, March 2024, N = 420 biopharma and MedTech organizations.

We also conducted in-depth discussions with 15 executives from biopharma and MedTech organizations to complement the survey findings.

The study findings reflect the views of the respondents to our online questionnaire for this research and are aimed at providing directional guidance. Please contact one of the Capgemini experts listed at the end of the report to discuss specific implications.

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