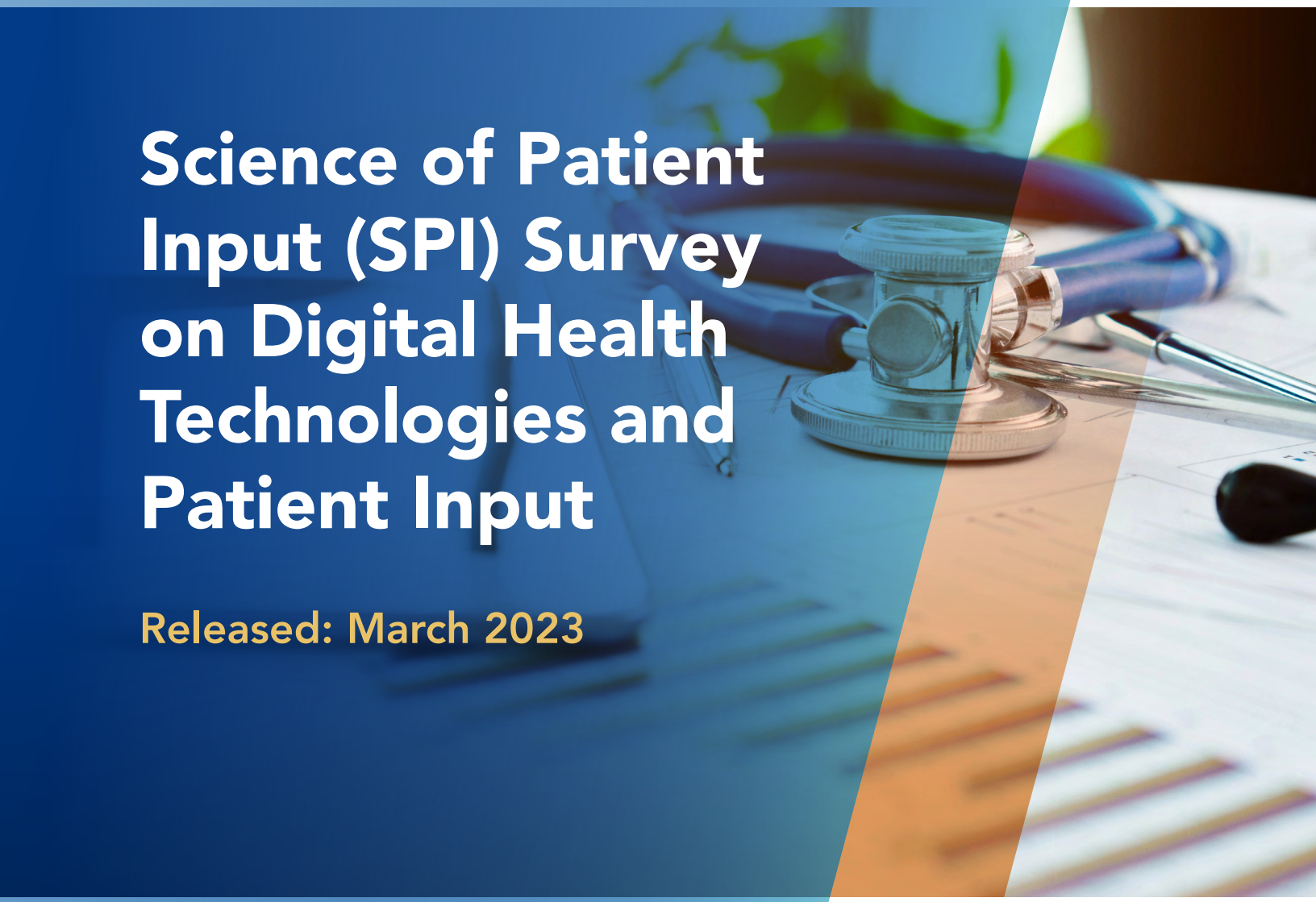
# Science of Patient Input (SPI) Survey on Digital Health Technologies and Patient Input



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MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

# Table of Contents


# Faster, safer, and more cost-effective innovation for patient patients.

# About MDIC

The Medical Device Innovation Consortium (MDIC) is the first public-private partnership created to advance the medical device regulatory process for patient benefit. MDIC was formed in 2012 to bring the U.S. Food and Drug Administration (FDA) and industry together to share vital knowledge that can help bring safe and effective devices in a cost-efficient manner to patients and providers more quickly. MDIC membership and participation are open to nonprofit, industry, and government organizations substantially involved in medical device research, development, treatment, education, promotion of public health, or expertise or interest in regulatory science.

## Background

MDIC is enabling a world with timely access to safe and cost-effective medical innovations to improve patients' lives. A key component of delivering on this vision is integrating patients' voices, values, and preferences into medical device development and decision-making. In pursuit of this vision, MDIC has undertaken a robust Science of Patient Input (SPI) program, catalyzing projects to advance and promote best practices in engaging patient input throughout the medical device product lifecycle and patient experience with digital health medical technologies.

## Science of Patient Input Program

MDIC's Science of Patient Input (SPI) program provides a venue for continued collaboration to advance the art and science of patient engagement in regulatory science, including advances in methodologies and tactical considerations for integrating the patient's perspective and preferences in the design, clinical development, and regulatory review of innovative medical technologies.

# Executive Summary of Science of Patient Input (SPI) Survey on Digital Health Technologies and Patient Input

MDIC designed a Science of Patient Input (SPI) survey to collect insights regarding the use of Digital Health Technologies (DHT) with a specific focus on generating data related to patient input that can be incorporated into the medical device ecosystem to drive future initiatives. The COVID-19 pandemic had expedited the adoption of digital health technologies and efforts to leverage them in understanding and incorporating patient input into the development of new medical technology and the delivery of care.

## Objective

The objective of the survey was to gather and evaluate input across stakeholder types to learn about the successes, challenges, and opportunities that exist in the DHT space.

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## Acknowledgment

MDIC would like to thank FTI Consulting, Inc. for their generous assistance and collaboration with the analysis of the survey data and the co-development of this report.

## The Stakeholders of Care Continuum

The assessment of survey data shows that the future MDIC SPI initiatives can help:

- Close the communication gap between patients and providers
- Create valuable and useful insights by integrating data from all sources, including clinical data stored in EHR
- Address Health Equity: best practices to ensure access to health for all communities, including the underserved
- Create best practices to provide patients access to their data
- Cybersecurity challenges with digital health data

## Survey Methodology

The survey comprised 157 questions targeting stakeholders in the medical device continuum to gather input on digital health adoption and patient-generated data utilization. Several stakeholders types were identified in the survey: patients, providers, hospital systems, investigators, manufacturers, and med-tech companies. A survey link was forwarded to each participant, based on the category of stakeholder they identified themselves as; they were each presented with a set of questions (Table 1 shows how the survey was organized).


For this survey, the term "Digital Health Technologies (DHT)" refers to:

- Computing platforms, connectivity, software, and sensors used broadly for applications in general wellness
- A medical product, software as a medical device (SaMD), within a medical product, as part of a combination product, or as an adjunct to other medical products (devices, drugs, and biologics).

The survey focused on gauging the perspectives and opinions of stakeholders concerning the following challenges and opportunities that exist in digital health adoption:

- Data health interoperability and integration,
- Data privacy and security,
- Health equity and accessibility, and
- Regulatory pathway.

| Survey metric summary | Hospital Systems | Investigators | Manufacturers | Med Tech / Other | Patients | Payers | Providers | Total |
|---|---|---|---|---|---|---|---|---|
| Total classified by segment | 1 | 33 | 60 | 50 | 37 | 3 | 17 | 201 |
| Average number of responses received | 1 | 19 | 26 | 30 | 24 | 0 | 14 | 114 |
| Average response rate (%) | 100% | 58% | 43% | 60% | 65% | 0% | 82% | 57% |
| Number of survey questions | 24 | 20 | 18 | 21 | 29 | 18 | 25 | 155 |

Table 1: The survey used a combination of open-ended questions, multiple-choice questions, and rating scale questions to achieve the study objective.

## Participation survey metrics or scope limitations:

The following observations and adjustments were made in assessing the survey responses:

- The original survey had payers enlisted as one of the key stakeholders. However, they have been excluded from the report because of a lack of response
- 53% of the provider survey respondents self-identified themselves as cardiology specialists.
- 74% of the MedTech device manufacturers that responded to the survey identified themselves as having R&D roles in the company
- Hospital systems have not been accounted for in the outcome section of the report because of the relatively small sample size compared to the other stakeholders.

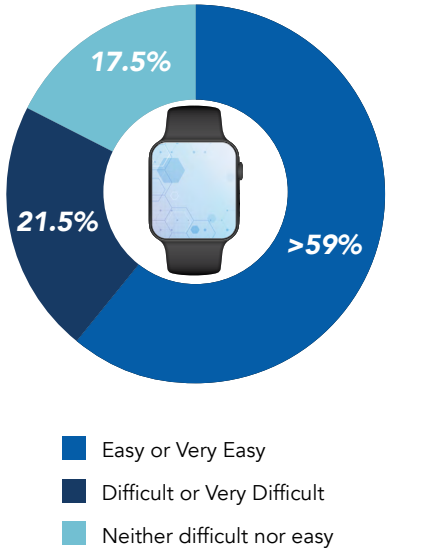
# Patients

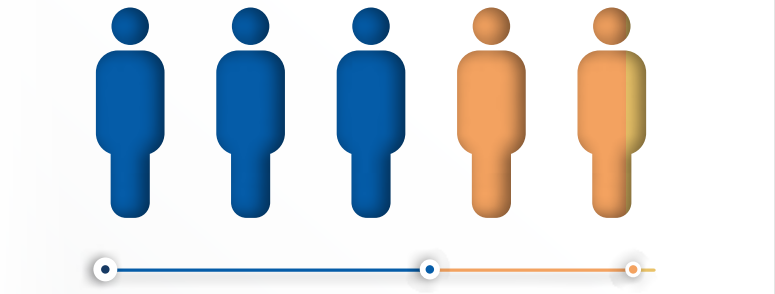
## Adopting digital technology: Wearable Devices

The role of digital technology has helped patients tremendously in managing their health. It can continue to significantly influence  them to manage their health and engage with their clinical care team more actively. Patients rated wearables as the most used medical device/health technology; **over 59% of the patients found accessing health data from their devices either easy or very easy** compared to 21.5% who found it to be difficult or very difficult and the remaining 17.5% who found it neither difficult nor easy.

There has been an increase in the utilization of digital health technologies among patients since the onset of covid - about 69% of the patients either started or increased digital adoption. There is a strong willingness among patients to manage their health and wellness - **96% of the respondents said they would either continue to use/be willing to start using wearable digital health technology devices to manage health and wellness in future devices**. One of the Patient Stakeholder interviewees, says she's aware of the cybersecurity issues and risking her sensitive PIH data, but the benefits of digital health outweigh the risk significantly.

**Patients accessing health data from wearable devices**



**65%** of the patients said that there has been "increased/improved" usefulness of consumer wearable

**96%** of the respondents said they will either continue to use/be willing to start using wearable digital health technology devices to manage health and wellness in the future

## Patients want Digital Health Integration

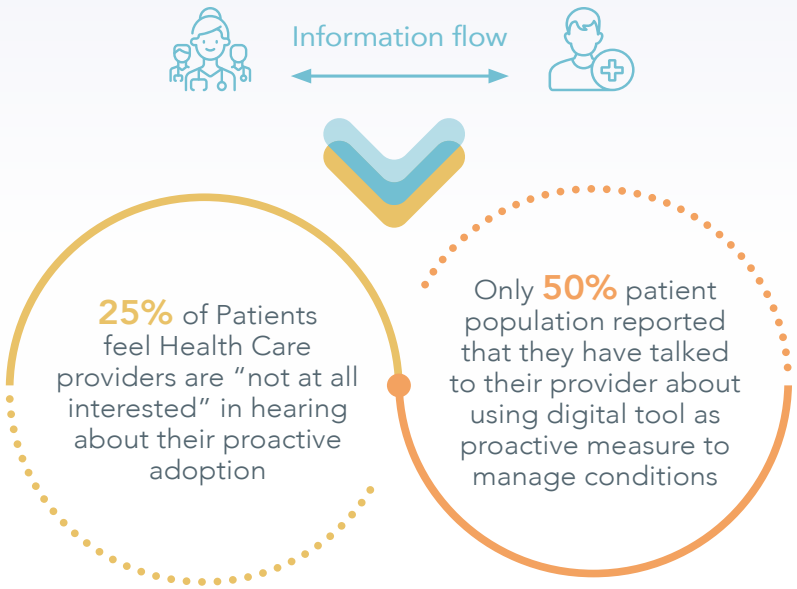
Integration of digital health information would allow patients and providers to pursue a holistic approach to healthcare and wellness. Patients, when asked to describe the barrier they confronted when adopting digital health tech, echoed  missing interoperability between devices and integration with electronic health records. Another Patient Stakeholder, a diabetic patient diagnosed in 1983, is an early adopter of digital technology who has a strong appreciation for the evolution of diabetes management technology from syringe/vial pumping to real-time feedback but continues to say, ***"One of the things that has been frustrating over the years is the interoperability of devices."*** Recalling the  several "data dumps" she was conducting from multiple devices on a weekly/biweekly basis because of the lack of interoperability between the blood sticks and the monitoring device for disease management a few years ago.

## Patients want to provide valuable Insights for their healthcare providers

Patients are proactively asserting control over their health by collecting and generating data. Patients want to see clinicians use this data as guiding rails to make educated decisions and optimize their care. However, these conversations are not happening. Only 50% voted "Yes" to talk to their HCP about using digital health technologies and wellness tools as a proactive measure to manage their condition. When asked about the level of interest from their HCP, the responses varied. The answers ranged from 25% for "Not at all interested" to 33.33% for "Very Interested." Over 56% of the patients stated that there had been "little/no impact" on the usefulness of consumer wearable devices data to be used by their healthcare provider. One of the patients said, "Doctors don't have time to review my home records in the 30-min appt. they primarily review only hospital medical test results & make snap decisions." Another patient, an adopter of FDA-approved digital apps for ovulation and wearable technology, expressed her lack of comfort with her primary care doctor: "In an ideal world, I would like to share everything with my physician" with a hope to take more informed decisions regarding nutrition and care.

### Patient/Provider Disconnect

Patient Engagement with their providers through conversational platform is critical to improving outcome of patients



# Providers

## Providers on digital adoption: Wearable Data is the most useful

A significant number of providers have either incorporated or recommended that their patients use digital health technologies. 93% of the respondents agreed that they have been working with their providers to adopt some level of digital health technology. Providers, self-identified as digital health tech users before the pandemic, have adopted remote patient monitoring and telemedicine that has enabled:

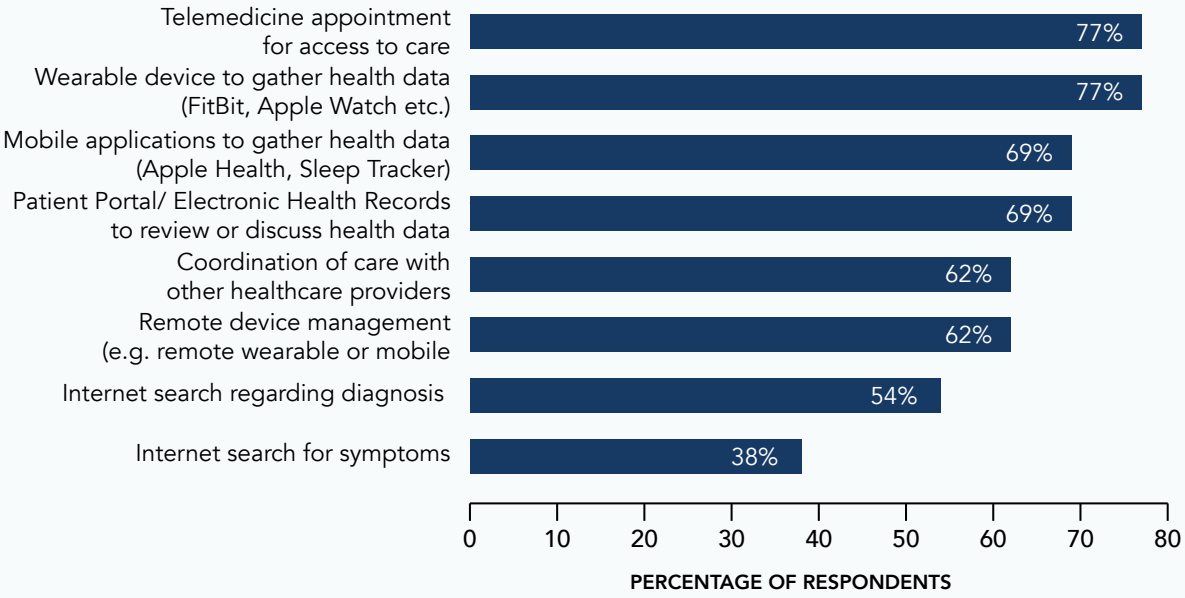
- increased access to patient data
- timely interaction with their patients and caregivers
- delivery of quality, affordable and efficient care

The most significant impact providers have observed is the high quality of care; over 85% share that sentiment. The two most important trends in digital technologies among providers have been using wearable devices to gather health data and conducting telemedicine appointments to access care. Providers have found wearables to be the "most useful" information source and patient diaries to be the least.

Providers found that wearable device data was found to be the **most useful**

Patient diaries were found to be the **least useful**

## What digital Health Technology have you used




**77%** of providers said they have used wearable devices and telemedicine.

Over **85%** of providers agree that digital technologies and digital health data has impacted their ability to deliver quality care.

**54%** of providers selected "wearable device data" as the most useful digital health information.

## Providers want patient empowerment & input

Providers that are strong proponents of digital health adoption agree that digital health technologies have helped patients become more proactive about managing their care. The three leading reasons for greater patient participation as per providers in this order of increased votes are:

- behavioral/lifestyle changes;
- compliance with care plans and;
- shared decision-making support.

> **Providers believe that access to patient insights and health data generated from digital tech efficiently and effectively supports conversations with patients about their care.**

*Respondents agreed that digital health technology has helped patients participate more in managing their care.*

**80%**

of respondents agreed that digital health technologies helped patients manage their care through **shared decision-making**

**70%**

of respondents concurred that digital technology enhanced **compliance with care plans and behavioral/ lifestyle changes**

## Providers on Data Integration – an increasing Challenge

Providers are looking at medical device companies to advance digital health innovation. They strongly believe that the prospect of valuable insights depends heavily on the interoperability and integration of these devices and data sources in a cyber-secure environment. One of the impacts of patient-generated data noted by providers is "increasing challenges with interoperability such as with EHR systems." More than half of them asserted the important role of wearables in the care continuum, given the consumerization of healthcare to be a "holistic approach to decision making."

# Hospital Systems

Hospital systems are ubiquitous users of digital health technologies for their day-to-day processes that find telemonitoring outputs to be the most beneficial. The survey and interview anecdotes reveal that remote patient monitoring, telemedicine, and patent access to digital health data have improved their ability to deliver care. One of the stakeholders interviewed described the digital health benefits to patients in the hospital as "life-changing" after receiving the right treatment for migraine after years of under-diagnosis because of a digital health app that helped doctors reassess the severity of migraines and thus reconsider treatment.

**Digital health technologies can improve a patient's care in a myraid of ways**

# Investigators

## Investigators adopting digital health: Wearables & Apps

**83%**

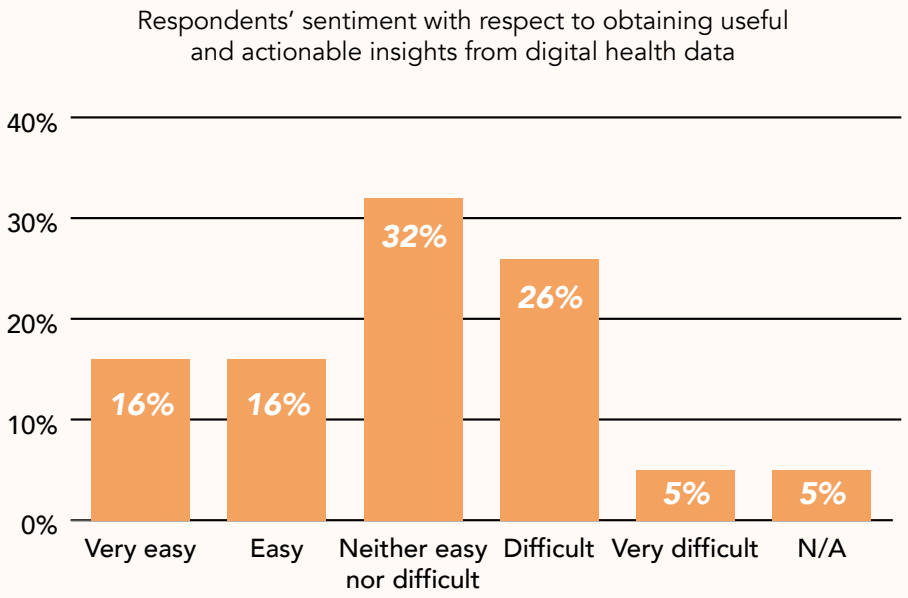
Investigators have incorporated digital health technologies in their clinical studies

Investigators have historically incorporated digital health technologies in their clinical studies to some degree before the onset of the pandemic. The most common digital health technologies utilized are wearable devices and health apps, including apple health and remote device management, with 64% of investigators selecting this option. Investigators believe digital health technologies help capture "real-world data" from patients. However, the coordination of care with other healthcare providers is much lower, at only 18% utilizing them for this purpose. Nevertheless, there were some common themes throughout the survey- the need for patients' access to data, health equity, and digital health's impact on clinical studies.

## Investigators want actionable insights

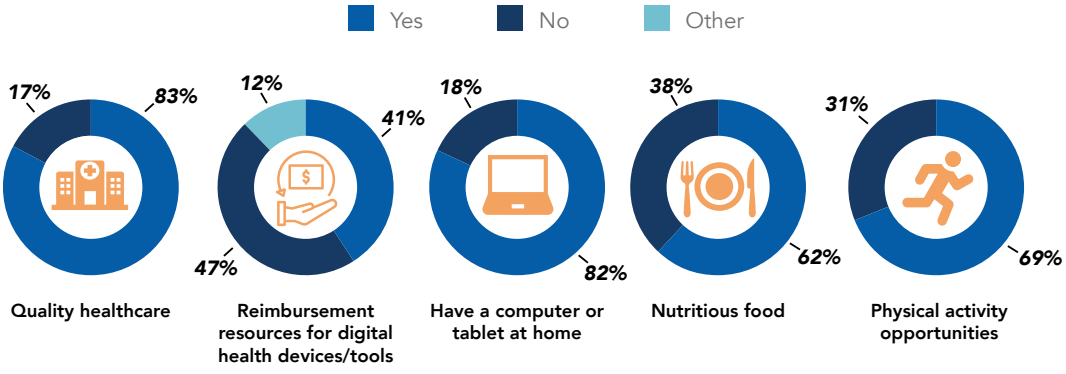
Data is constantly collected, and there is an increase in patient-generated data from digital health technologies. Therefore, it is essential to understand how it impacts clinical research and how easy it is for investigators to obtain actionable insights into the data received. One-third of investigators found it "neither easy nor difficult," and little over 26% found it "difficult to obtain actionable insights from the data that they received". However, **63% believe the increase in patient-generated data expands the opportunity to offer clinical research studies.**

### Patient access to data



## Health Equity

Healthy equity is a national imperative, and technology is critical in helping close that gap. For example, **74% of investigators agreed that digital health technology would expand access to clinical research within underserved communities**. Roughly 83% of investigators believe their patients have access to quality healthcare. However, 17% believe their study participants generally do not have access to quality healthcare. Regarding reimbursement for digital health devices/tools, **47% of investigators typically feel that their study participants do not have access to financial support**. Most investigators think that their study participants have access to a computer at home and generally have access to nutritious food and opportunities to get physical activity. **However, this information can be biased by the current patient populations in that investigators are now engaged. Increased outreach to underserved patients and communities could significantly change this impression.** One community that a few of the interview participants felt is being under severed is the population with disabilities. **"They never really accommodate those things so even when we're trying to bring digital technology or education to a different demographic, they aren't necessarily ADA compliant"**- *Investigator Stakeholder*




# MedTech

## MedTech on Digital Health Adoption: increase in telemedicine

Many of the participants in MedTech believe that digital health technologies have increased since the start of the covid-19 pandemic. More than 60% of MedTech believe that there has been increased usage of digital health technologies like wearables and health apps, from supporting diagnosis to researching symptoms. In addition, almost all MedTech survey participants believe there has been an increase in telemedicine appointments. The most prevalent themes throughout the MedTech survey were digital health data integration, compliance, and patient access to data.

## MedTech on Challenges of Digital Health

Although there are many advantages to using technology, there are also challenges. Some of the study participants believe that providers need to educate patients on digital health benefits and that there needs to be more interoperability and digital health integration. ***"Tech should make our life easier and not create new activities that increase the burden of care."*** Some of the common themes for MedTech include making it easier to use the data and making sure that it integrates into existing platforms and tools. Other challenges include regulatory challenges and navigating the different regulatory bodies, whether its U.S or Europe. As well as understanding what different regulatory bodies classify as a medical device, something that might be approved as a medical device by the FDA in the U.S might not necessarily be a medical device in Europe as per the EU regulations.

Lack of Standards

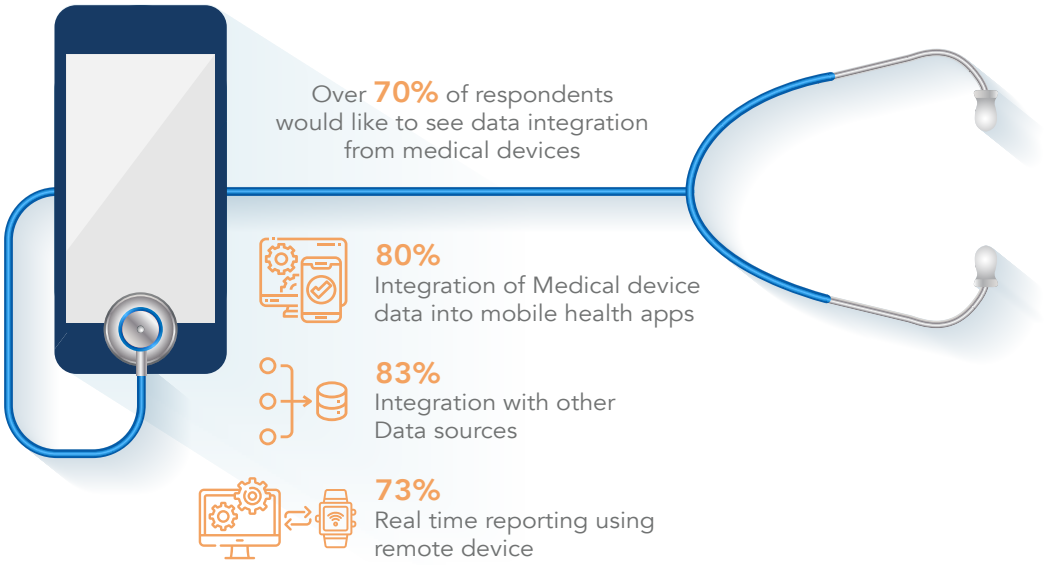
Understanding potential security risk

Applying data security across Platforms

Other

## Impact of Digital Health Technologies

The integration of digital health technologies has had a positive effect. **The survey reported a 53% improvement in quality of care and a 73% improvement in the efficiency of providing care or patient information.** There has also been an impact in interaction across the healthcare continuum (doctors, patients, providers systems), with 67% seeing an improvement. **Over 70% of respondents would like to see data integration with medical devices and integration across data sources and health apps.** Currently, only 14% find it easy to access data to create valuable, actionable insights from digital health technologies, 48% of the participants feel that it is neither easy nor difficult to access data, and 37% find it difficult. Having access to data will help patients with accountability regarding their health.




## Value

Digital health technologies can help in many ways. One example is the *"use of various digital health technologies to implement decentralized trials."* MedTech believes that digital health tools can help patients be more accountable. Setting goals, performance monitoring, and data-driven conversations between doctors and patients ranked the highest with 75%.

**Participants also responded very positively (92%) that healthcare providers could use digital health and wellness tools to manage patient health proactively.**

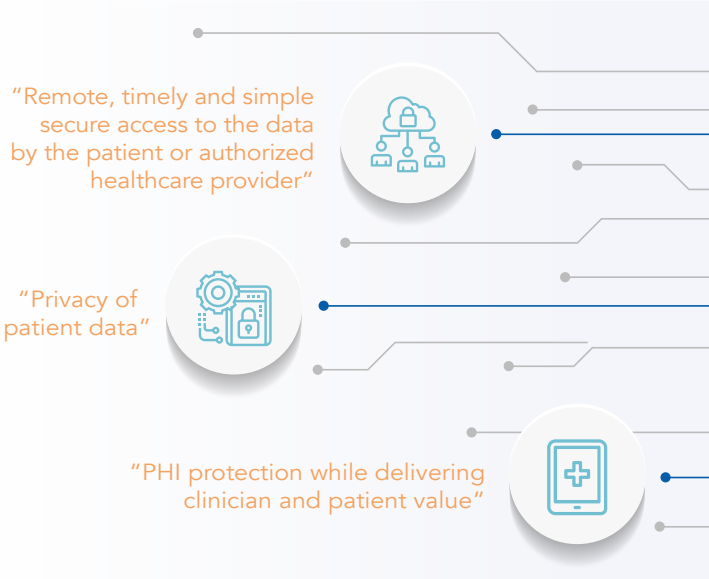
# Data Security & Privacy

## Med Device on Data Security & Privacy

As result of the pandemic, **85% of manufacturers believe there has been a change in demand for their company to develop more innovative digital health technologies.** As more products are designed and digitized, there is a potential risk for cybersecurity issues in medical devices, wearables, and mobile apps.

**86% of respondents recognize that data security regarding digital health technologies is extremely important and a growing area..**

Respondents noted that some of the challenges of using data from digital health technologies included the privacy of patient data.




## Regulatory

Technology is constantly evolving, but healthcare is more rigorously regulated, making it more challenging for medical device manufacturers to innovate, unlike other tech industries. Respondents concurred that addressing regulatory concerns regarding patient compliance with instructions provided via digital health tools is essential and challenging. 73% of manufacturing respondents noted that support for remote device management was the most requested digital health technology for patient care. Respondents indicated that regulatory challenges exist when medical devices and consumer devices are being used to develop data to support clinical studies. **"The current regulatory framework is not conducive for expeditiously providing safe digital products to help advance health research."** However, one of the survey interviewees found that **"I did not find any difficulty... the FDA has come to a level where they have a very good understanding of the technology evolution, which was a little bit hard to imagine, five years ago."**
*- Medical Device Stakeholder.*

## Clinical Studies

Manufacturers believe that medical devices can be of significant value to clinical studies. For example, **"Wearables could replace office/clinically-based visits by ensuring minimal missing data" additionally, 89% of respondents agreed that remote patient monitoring, telemedicine, and access to patients' health data would further enhance clinical research.** As technologies evolve, some features/functions that manufacturers would be interested in seeing in the future are **"Seamless integration into clinical trial platforms with high quality of information/signals."**

**73%**

of manufacturing respondents noted that support for remote device management was the most requested digital health technology for patient care

**88%**

of respondents concurred that digital health technology could play a significant role in real-time insights for patients and clinicians

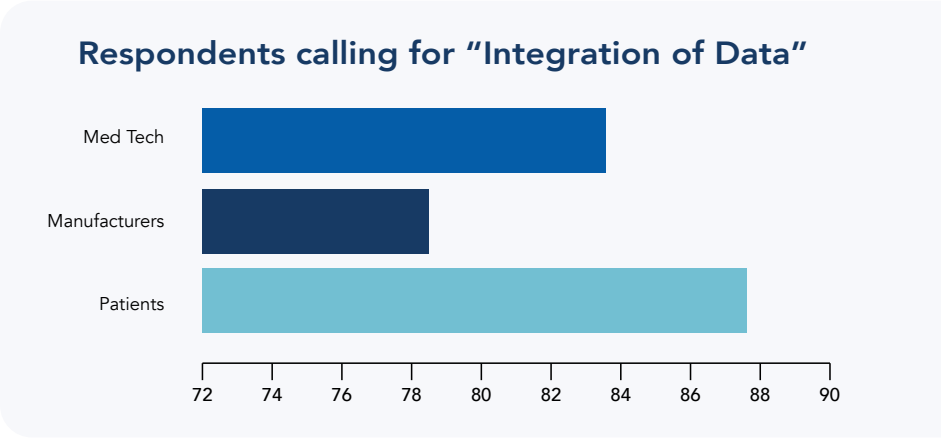
# Key Themes

## Utilization of Digital Health Tech: Wearable Devices

Wearable technology is becoming a primary digital health tech tool across the continuum of care. Each stakeholder shown below uses wearables to manage their health or their patients' health. The role of wearable tech may vary in each case. Still, the power of getting real-time insights, capturing real-world data, and offering the support of shared decision-making enables these stakeholders to accomplish their role in the value chain of care delivery.

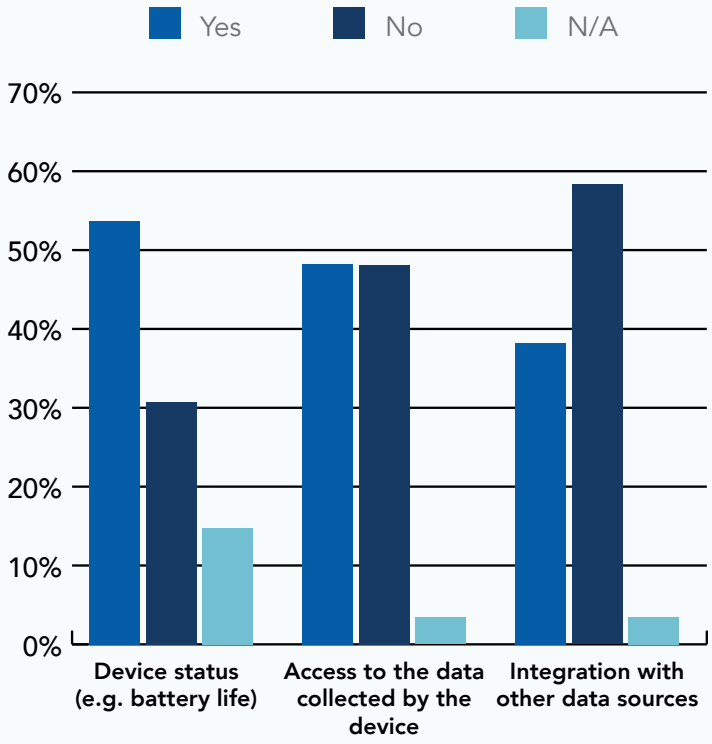
## Data Access and Integration with other sources

The post-pandemic settings has triggered the adoption of digital tech among patients and increased the use of digital medical records such as EHR in the last 18 months, as per the survey. This heightened awareness of digital tech in the patient population beyond wearable technology points to their frustrations for lack of visibility to the collected data.

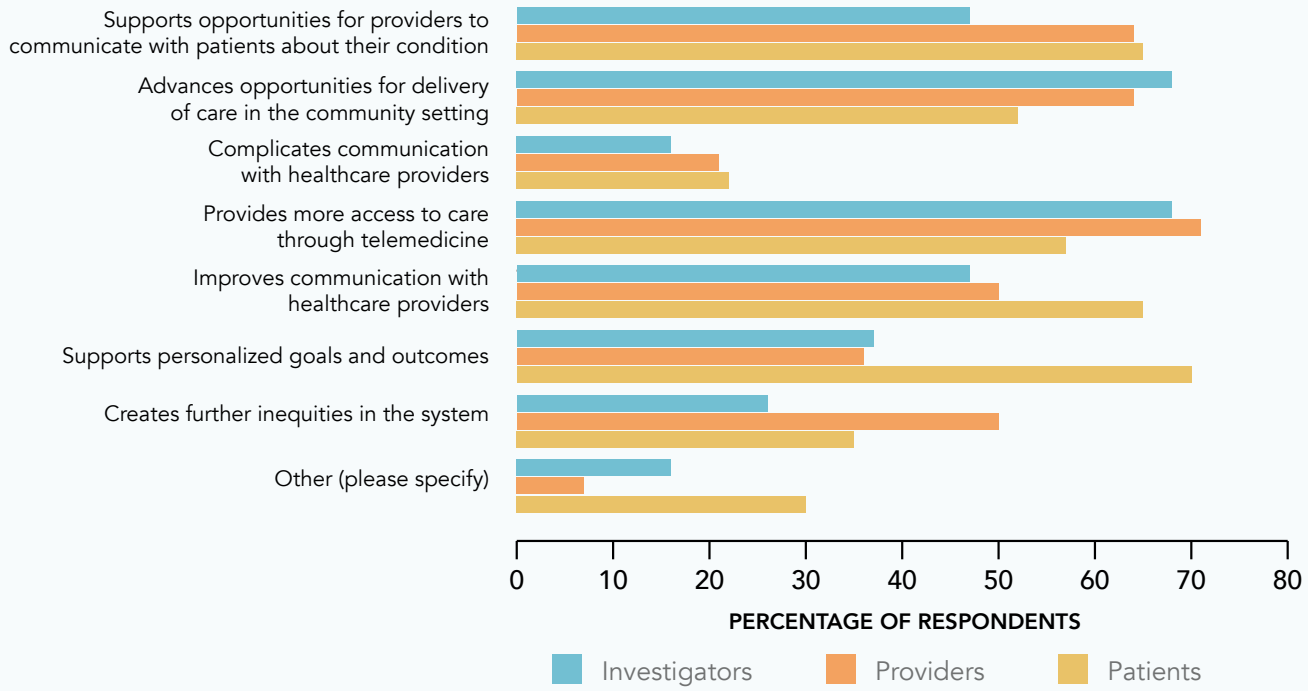



Patients expressed that they want ownership of the data they currently don't have access to. As per the survey, **95% of the patients voted for "access to information collected by the medical device," and more than 87% voted for "integration with other data sources."** As shown above, MedTech innovators and manufacturers of medical products are less in comparison when identifying these challenges. The missing integration between patient-generated data and clinical records is an obvious pain point that needs to be relayed to industry leaders. Similarly, providers cannot fully experience the impact of digital health technologies because of the increased challenges with interoperability, such as between different EHR systems.

## What data is currently accessible to Patients?




**What do you think is the impact of digital health technologies on delivery of healthcare for underserved and diverse communities?**



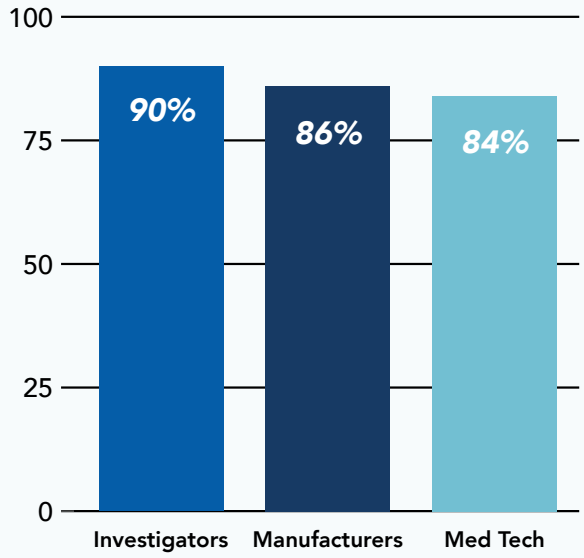

## Health Equity

Regarding health equity across the different stakeholders, the various stakeholders recognize that it is a national imperative. The survey data suggests that telemedicine has been instrumental in making care more accessible to underserved and diverse communities. The impact of digital health in care delivery has been observed at a community level. As these health equity and accessibility issues are being realized, industry leaders are taking deliberate initiatives to address them; **73% of manufacturer respondents agreed that their company has programs that specifically focus on diversity, inclusion, and health equity.**

## Cybersecurity Concerns

The increasing digital data, and the risks to security and privacy of patient records and communications are directly proportional. **All the stakeholders surveyed on this issue, rated the importance of data security regarding their use of digital health technologies such as for clinical research and as part of product development, as highly important.**

**Stakeholders weigh in on importance of data security in digital health technologies**




## Information and conversation gap

While digital technology evolution, innovation, and adoption are emerging around us, it's missing a platform where physicians can engage with patients seamlessly with a more robust and connected view of holistic personal health to improve patient outcomes. Providers want medical device companies to advance digital health technologies to educate the end-users of care delivery; **93% believe patient education is key to ensuring advancement**. Similarly, while patients are wide adopters of wearable technology, they believe the generated information has little to no impact on providers. **50% of the patients said they hadn't discussed digital health technologies with their providers.** The survey demonstrated **a similar disconnect when talking about cybersecurity - despite 3/4 of patient participants having rated cybersecurity as a critical issue for them, only 1/5 of the providers thought that patients view cybersecurity as a challenge.**

# Conclusion and Recommendations

The pandemic has fast-tracked the adoption of digital tech among patients, increased the use of digital medical record systems such as EHR, and expanded care accessibility through telemedicine solutions. The heightened awareness of digital tech among the patient population beyond wearable technology is promising but also highlights the challenges and frustrations that come with it. The survey details the concerns with cybersecurity and the protection of patient health data. Specifically, the security and integrity of this sensitive data cannot be compromised, impact clinical outcomes, and compromise the patient's health. More safeguards will need to be considered for EHRs, medical records, health data on mobile phones, remote monitoring devices, etc. Ongoing investment in cyber risk management should continue to be at the forefront of digital innovation in life sciences.

There is consensus in the care continuum that digital health is the path forward for achieving health equity and making health accessible to underserved patients and communities. Telemedicine has been instrumental in providing care to patients in remote locations and offering follow-up services directly from physicians and care providers.

However, the data shows that these underserved communities lack a safe, secure, and reliable communication infrastructure and platform that will allow physicians and care providers to push the correct information to patients in their care journey and enable meaningful conversations for alignment around data privacy, data integration, and overall digital adoption. The survey analysis revealed the disconnect between how providers perceive their patients' concerns and what they are. Better communication practices and mobile apps providing end-to-end actionable insights will alleviate misunderstandings and spur helpful discussions.

**Continued collaboration between industry leaders, innovators, care delivery experts, and end-users (i.e., the patients) is needed to further push digital health's boundaries. The drive to change the status quo and achieve more effective, improved quality, and affordable care will empower patients and improve their clinical outcomes.**

The US FDA did not design or execute this survey, and the survey results and conclusions do not reflect the position of FDA in any pertaining areas. The Medical Device Innovation Consortium (MDIC) is the first Public-Private partnership created to advance the medical device regulatory process for patient benefit. MDIC was formed over a decade ago to bring the U.S. Food and Drug Administration (FDA) and industry together to share vital knowledge that can help bring safe and effective devices in a cost-efficient manner to patients.

This report and survey was made possible thanks to the science of patient input working group members representing Patients, Patient Advocates, Device Manufacturers, Researchers, Non-profits and the FDA.

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# Thank you!

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