Digital Health Survey

A Slide Deck of the Science of Patient Input (SPI) Program of the Medical Device Innovation Consortium (MDIC)
# Table of Contents

- Introduction 3
- Patients 4
- Providers 5
- Investigators 6
- Manufacturers 7
- Hospital systems 8
- Med Tech / Other 9
- Summary output 10
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.

Medical Device Innovation Consortium (MDIC) is working to enable a world with timely access to safe and cost-effective medical innovations that can improve patient’s lives. A key component of delivering on this vision is to ensure integration of patients’ voices, values, and preferences in medical device development and decision-making. In pursuit of this vision, MDIC has undertaken a robust Science of Patient Input (SPI) program, which catalyzes 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.

MDIC 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.
The COVID-19 pandemic has expedited 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. This survey aims to gather and evaluate input from across stakeholder types to learn about the successes, challenges, and opportunities that exist in this space.

### Survey metric summary

<table>
<thead>
<tr>
<th></th>
<th>Hospital Systems</th>
<th>Investigators</th>
<th>Manufacturers</th>
<th>Med Tech / Other</th>
<th>Patients</th>
<th>Payers</th>
<th>Providers</th>
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<tr>
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<td>30</td>
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<td>0</td>
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<tr>
<td>Average number of responses by segment (%)</td>
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<td>43%</td>
<td>60%</td>
<td>65%</td>
<td>0%</td>
<td>82%</td>
<td>58%</td>
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<td>18</td>
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Prepared by MDIC and FTI
Digital health data integration
Integration of all digital health information would allow patients and providers to pursue a holistic approach to health care and wellness.

87.5% of respondents want their device to integrate with other data sources.

Data security & privacy
The majority of respondents rated data security for digital health and digital initiatives as being of the highest importance.

75%

In addition to data privacy concerns, a common theme from respondents was how they could access their own diagnostic data.

95% of respondents want to use digital health technologies and information to self manage health conditions with more control and access to their own health data.

Health Equity & access
Respondents felt that there is a digital divide and under-served communities lack access to technology, are hindered by broadband costs, and suffer from health literacy.

Upwards of 70% of respondents believe that the greatest impact of digital health technologies on the delivery of healthcare for underserved and diverse communities would support personalized goals and outcome.

Less than 50% of respondents received financial/reimbursement resources to access digital health technologies.
### MDIC – Science of Patient Input: Providers

#### Using data for clinical care

With continuous innovation in wearable digital health technology, there has been an improvement in quality of care for patients by providers. **86%** of respondents agreed that remote patient monitoring, telemedicine, and patient access to health data has improved quality of care for patients.

Providers found that wearable device data was found to be the most useful. Patient diaries were found to be the least useful.

#### Health equity

**71%** of respondents agreed that digital health technology provides more access to care through telemedicine within underserved communities.

### Patient empowerment & input

- **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.

### Digital Health Data Integration

Over **76%** of provider respondents agreed that the increase in patient generated data from digital health technologies would be most impacted by challenges with interoperability such as, with EHR systems.

- All respondents agreed that there is a role for medical device companies in advancing productive use of digital health technologies for patient care and quality of care.

  - "Better integration with EHR."
  - "Easy integration into EHR."

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**MDIC Consulting**
MDIC – Science of Patient Input: Investigators

**Patient access to data**
Respondent’s sentiment with respect to obtaining useful and actionable insights from digital health data

- 16% Very easy
- 16% Easy
- 32% Neither easy nor difficult
- 26% Difficult
- 5% Very difficult
- 5% N/A

76% of respondents believe digital healthcare information is accessible to study participants
53% of respondents found patient data easy to understand

**Clinical studies**
83% of respondents have incorporated the use of digital health technologies in clinical studies

Nearly 70% of participants believe that digital health technologies affect how they conduct their studies

More than 75% use digital health technologies for protocols, consent forms, and IRB/ethics committees

**Health equity & access**
74% of respondents agreed that digital health technology would expand opportunities for access to clinical research within underserved communities

**Patient access to digital health technology**

- 17% Quality healthcare
- 47% Reimbursement resources for digital health devices/tools
- 18% Have a computer or tablet at home
- 58% Nutritious food
- 31% Physical activity opportunities

Yes 83%
No 17%
Other 0%

- Other
- Yes
- No
Respondents agreed that data security regarding digital health technologies was considered to be extremely important with 86% of respondents selecting this option.

73% of manufacturing respondents noted that support for remote device management was the most requested digital health technology for patient care.

Additionally, respondents noted that regulatory challenges exist when medical devices and consumer devices are both being used to develop data for clinical studies.

"[The] current regulatory framework is not conducive for expeditiously providing safe digital products to help advancing health research."

MDIC – Science of Patient Input: Medical device manufacturers

Health equity & access

73% of respondents agreed that their company has programs that specifically focus on diversity, inclusion and health equity.

Data security & privacy

Respondents agreed that data security regarding digital health technologies was considered to be extremely important with 86% of respondents selecting this option.

Respondents noted that some of the challenges of using data from digital health technologies included:

- "Privacy of patient data"
- "Remote, timely and simple secure access to the data by the patient or authorized healthcare provider"
- "PHI protection while delivering clinician and patient value"

Clinical Studies

Artificial Intelligence (AI), Machine Learning (ML), and Real-world Evidence (RWE) is key and it can disrupt the way clinical studies are performed.

89% of respondents agreed that remote patient monitoring, telemedicine, and access to patient’s health data would further enhance clinical research.

88% of respondents concurred that digital health technology could play a significant role in real-time insights for patients and clinicians.
MDIC – Science of Patient Input: Hospital Systems*

Using data for clinical care

Digital health technologies can improve a patient’s care in a myriad of ways

Using data for clinical care

Digital health technologies can improve a patient’s care in a myriad of ways

Data security & privacy

“There is an awareness of vulnerabilities and a feeling that all bases have not been covered.”

Hospital systems encounter cyber security challenges for data from digital health technologies, including medical devices, wearables, and mobile apps

Patient empowerment & input

Wearable digital health technology plays a vital role in the care continuum with connected wellness to healthcare, holistic approaches to decision making, and real-time insights for patients being the most positive elements

Health equity & access

The care continuum can also be applied in underserved and diverse communities should the proper elements be in place.

“One first has to assure that members of these communities have ways to interact with technology. Connected devices have no use when patients have no connectivity to data services. Once connectivity is assured, the positive attributes of tech may be realized.”

Note: Only one respondent provided survey responses for the hospital system and therefore themes were difficult to fully identify.

*Only one Hospital System participated in Survey
MDIC—Science of Patient Input: Med Tech / Other

Digital health data integration
AI is needed to analyze and evaluate digital health information to be actionable for providers and patients in a simple and straightforward way.

- **83%** Integration with other data sources
- **80%** Integration of medical device data into consumer mobile health apps
- **73%** Near real-time reporting of adverse events using remote device mgmt.

Respondents noted that AI would be most impactful to patients going forward:
- "Interoperability of health platforms with the devices AI…"
- "The device providing personalized insights/correlations based on the patient data, using AI…"

Regulatory
Regulators can push toward “patient focused med tech” similar to “patient focused drug development”

Respondents noted that collaboration with the FDA regarding digital health technology for the Med Tech industry is essential to ensure regulatory is keeping pace:

- "Regulations are typically behind the cutting edge of technology. Digital health moves so quickly that FDA needs assistance from MedTech to keep up to speed."

Challenges of medical technologies and data cybersecurity
- Lack of Standards
- Understanding potential security risk
- Applying data security across Platforms
- Other

Patient access to data
More than **66%** of respondents believe that Access to data has improved Quality of care, efficiency in patient care/information.

- **38%** find it is difficult to access data to create useful and actionable insights.

Over **70%** of respondents would like to see data integration from medical device:
- **80%** Integration of Medical device data into mobile health apps
- **83%** Integration with other Data sources
- **73%** Real time reporting using remote device

Respondents noted that:
- Regulatory
  - Regulators can push toward “patient focused med tech” similar to “patient focused drug development”
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  - **83%** Integration with other Data sources
  - **73%** Real time reporting using remote device
Upon review of the summary data from the responses of the survey, common key themes became evident across the various segments including – privacy and data security, real-time data or RWE, and bringing digital health to underserved communities.
Appendix

**Medical Device Manufacturers** – this category of Stakeholders includes traditional medical device companies that develop regulated medical products. These products tend to impact the physical and mechanical function of the body.

- When choosing this option, respondents further specified their role within the medical device manufacturer organization. Based on engagement with patients/end users, individuals had different perspectives on the impact of digital health technologies.

- **R&D/Product** – individuals who conceptualize a device/product design that can meet the desired function and safety precautions
- **Developers/Engineers** – individuals that build the medical device/product based on the medical device design requirements.
- **Customer Facing** – this group includes sales representatives, customer service representatives, or any individuals that are subject matter experts of the medical device/product that can provide support, whether informational or instructional, to the end-user (providers and/or patients)

**MedTech/Other** – MedTech, or medical technology, is every product, service, or solution using medical technology to improve people’s health by preventing, diagnosing, monitoring, and treating disease. MedTech companies integrate features in their product offerings, including digital well-being, virtual care, and remote monitoring. Many of these products and services are not regulated by FDA, however, they provide valuable information to patients, providers, and investigators.

- **Hospital** – an institution providing medical and surgical treatment and nursing care for sick or injured people
- **Patient** – a person receiving or registered to receive medical treatment
- **Provider** – a doctor of medicine or osteopathy who is authorized to practice medicine or surgery (as appropriate) by the State in which the doctor practices
Thank you to all of the stakeholders that participated and provided input for the MDIC Science of Patient Input digital health survey.

### MDIC Digital Health Working Group Members:

<table>
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<th>Members</th>
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<td>Boston Scientific, Edwards Lifesciences</td>
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<tr>
<td>April Veoukas</td>
<td>Exact Sciences, Illumina</td>
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<td>Brian Edwards</td>
<td>Johnson &amp; Johnson, FDA (CDRH)</td>
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<td>Alissa Hanna</td>
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<td>Heather Colvin</td>
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<td>Liliana Rincon-Gonzalez</td>
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<td>Ami Mehr</td>
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<td>Wendy Selig</td>
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* Did not design or execute the survey
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MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM