

Multi-Stakeholder Survey on Use of Digital Health Tools Transforming the Process for Development and Use of Medical Device Technologies

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Speakers:

- Heidi Dohse, Tour de Heart
- Anindita Saha, U.S. Food and Drug Administration
- Heather Colvin, Johnson & Johnson



Session Agenda:

- Overview of the MDIC Digital Health project findings (20 min)
- Medtech challenges and opportunities (10 min)
- FDA-CDRH's perspective on patient-generated health data and use of digital health technologies (10 min)
- Q&A discussion (15 min)



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.

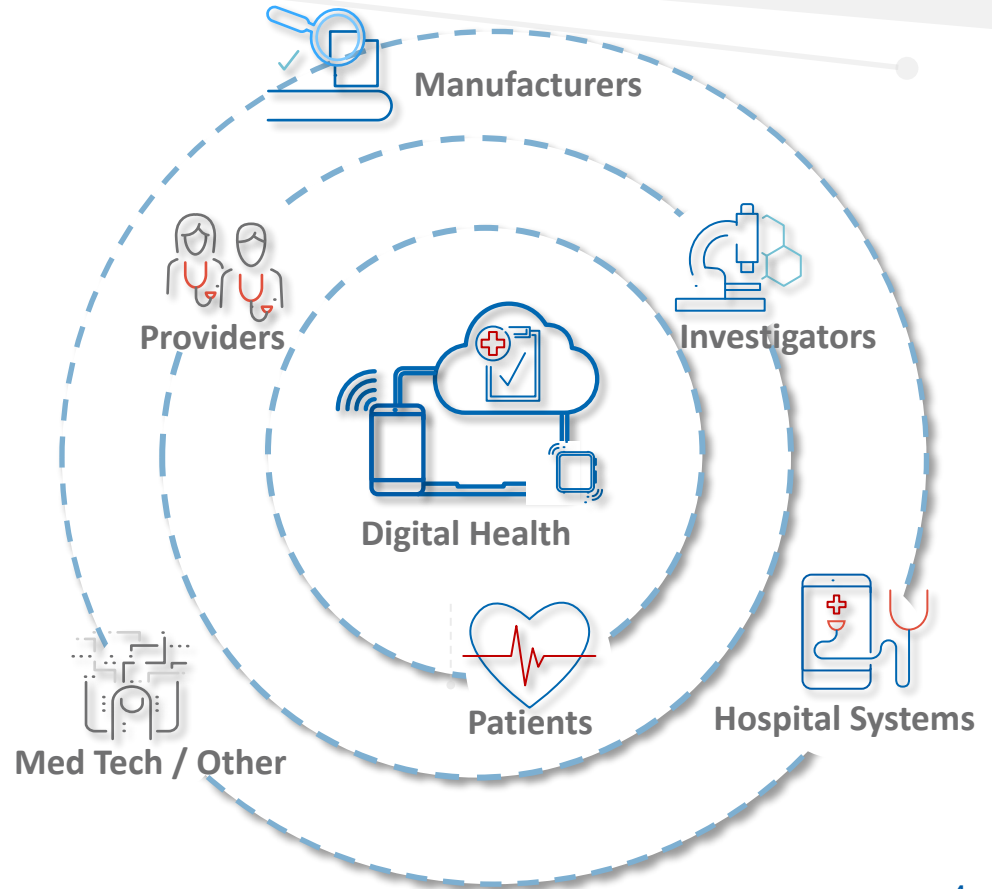
MDIC Science of Patient Input Program

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.



MDIC – Digital Health Survey: Stakeholder Overview

- Patients
- Providers
- Investigators
- Medical Device Manufacturers
- Hospital Systems
- Med Tech / Other



It is time for poll question #1:

What stakeholder group do you represent?

1. Patient
2. Investigator/Researcher
3. Healthcare Provider
4. Health System
5. Industry (Med Tech/Device

MDIC – SPI Digital Health Survey Metrics

Objective

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	Hospital Systems	Investigators	Manufacturers	Med Tech / Other	Patients	Payers	Providers	Total
Total classified by segment	1	33	60	50	37	3	17	201
Total responses received (avg.)	1	19	26	30	24	0	14	16
Average number of responses by segment (%)	100%	58%	43%	60%	65%	0%	82%	58%
Number of survey questions	24	20	18	21	29	18	25	157

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MDIC Science of Patient Input Digital Health Stakeholders

Data to live my life... and keep my Doctors in the Loop

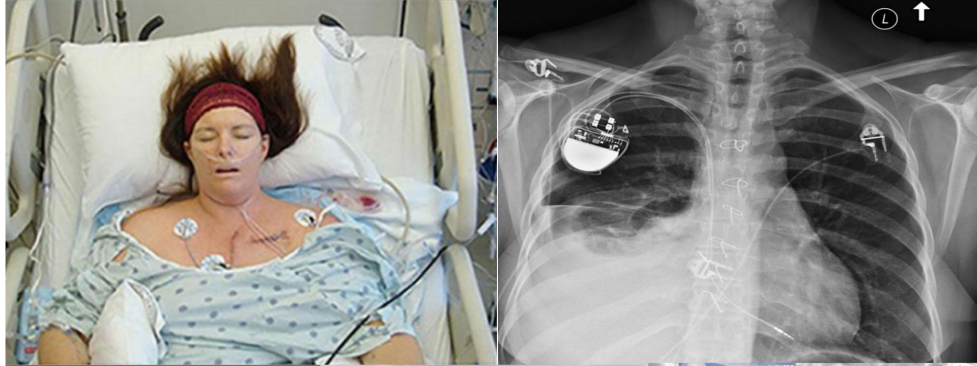
I have relied on medical devices for 37 years.

100% dependent on a pacemaker (on my seventh one).

Current Boston Scientific device collects data on every heartbeat, checks for abnormal rhythms, and monitors voltage settings and battery life. The information is transferred via a wireless communicator and made available to doctor for analysis. My Apple watch provides real-time insights in the context of living my life.



Your heart, Your mind



 **TOUR** *de* **HEART**



Is it working... Is it working... Is it working?



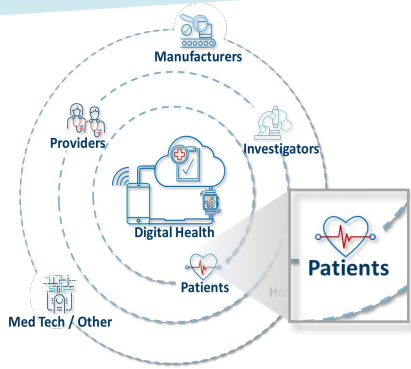
Overcoming the fear: Help me feel safe!

It is time for poll question #2:

Do you currently use a digital health or wellness tool (e.g., apps, wearable like an Apple Watch or Fitbit)?

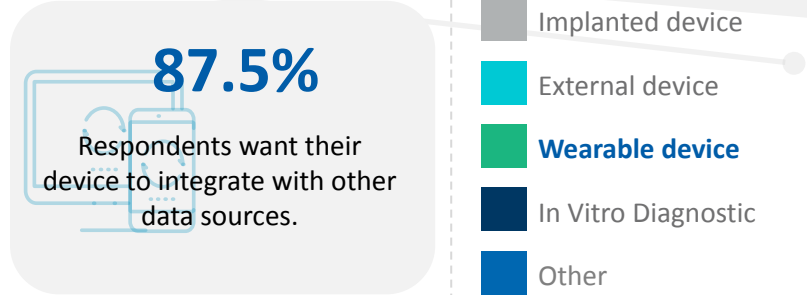
- Yes
- No

MDIC – Science of Patient Input: Patients



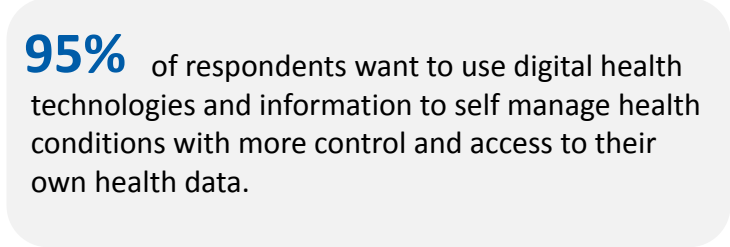
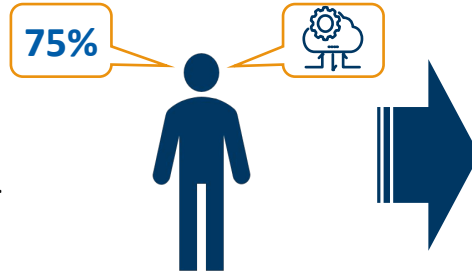
Digital health data integration

Integration of all digital health information would allow patients and providers to pursue a holistic approach to health care and wellness.



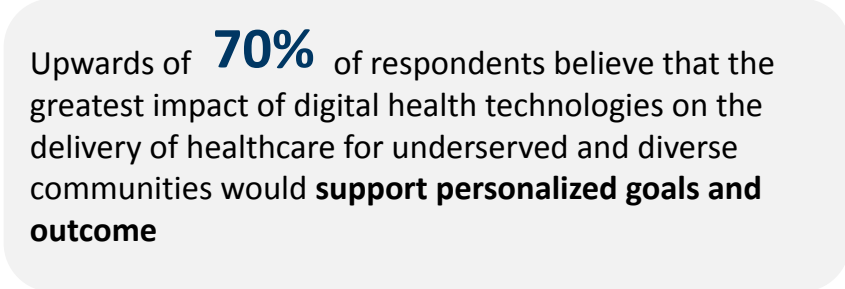
Data Security & Privacy

The majority of respondents rated data security for digital health and digital initiatives as being important.

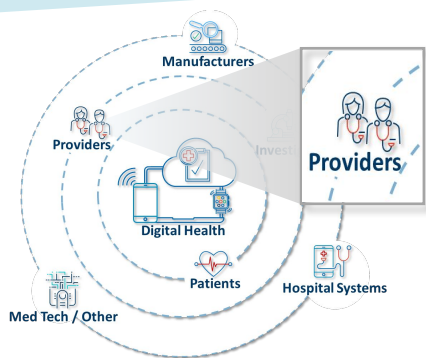


Health Equity & Access

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.



MDIC – Science of Patient Input: Providers

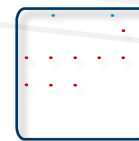


Using data for clinical care

86% of respondents agreed that remote patient monitoring, telemedicine, and patient access to health data has improved quality of care for patients



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

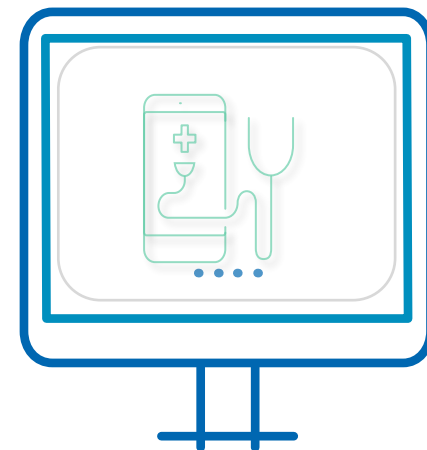
80% of respondents agreed that digital health technologies helped patients manage their care through **shared decision-making**

-&-

70% of respondents concurred that digital technology enhanced **compliance with care plans and behavioral/lifestyle changes**

Digital Health Data Integration

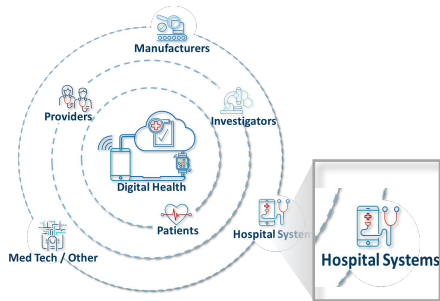
Over **76%** of provider respondents agreed that the increase in patient generated data from digital health technologies would be most impacted by **challenges with interoperability** such as, with EHR systems



"Better integration with EHR."

"Easy integration into EHR."

MDIC – Science of Patient Input: Hospital Systems*

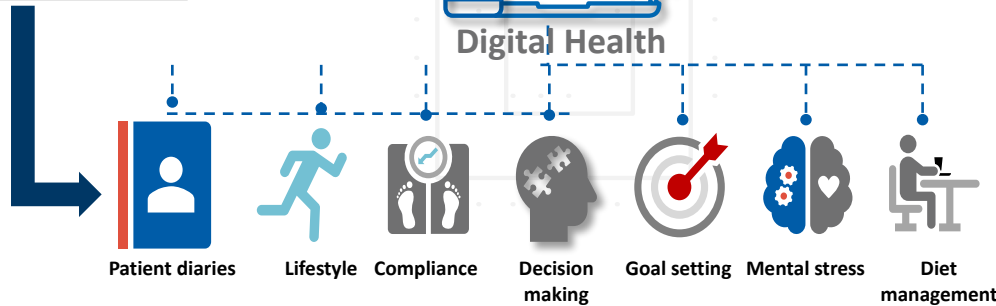


Using data for clinical care

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



Digital Health



Regulatory

Regulatory challenges are among the many hurdles that hospital systems face when collecting patient health data from digital health technologies

*Only one Hospital System participated in Survey

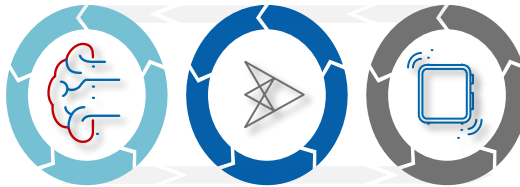
Data security & privacy

"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."

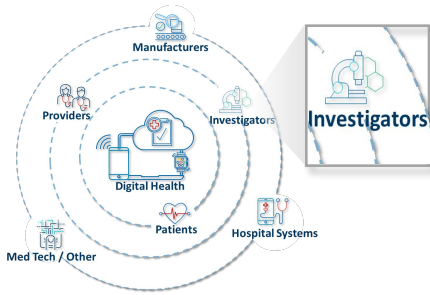
Note: Only one respondent provided survey responses for the hospital system and therefore themes were difficult to fully identify

It is time for poll question #3:

Would you be willing to let your data be used in research?

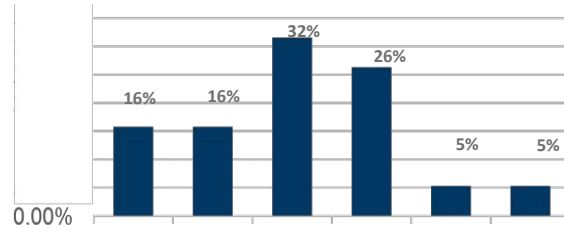
- Yes
- No

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



76% of respondents believe digital healthcare information is accessible to study participants

53% of respondents found patient data easy to understand



Clinical studies



83%

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

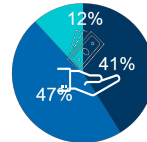
Health equity & access

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

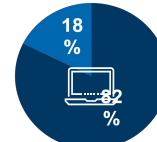
Patient access to digital health technology



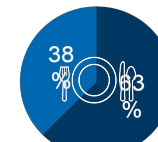
Quality healthcare



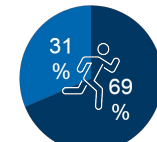
Reimbursement resources for digital health devices/tools



Have a computer or tablet at home



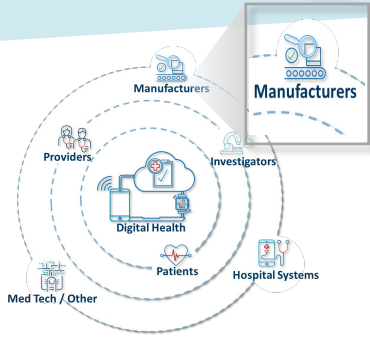
Nutritious food



Physical activity opportunities

Yes ■
No ■
Other ■

MDIC – Science of Patient Input: Medical device manufacturers



Regulatory

Respondents concurred that there are regulatory concerns regarding patient compliance with instructions provided via digital health tools

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

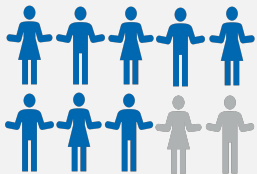


Additionally, respondents noted that regulatory challenges exist when medical devices and consumer devices are both being used to develop data for clinical studies

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

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

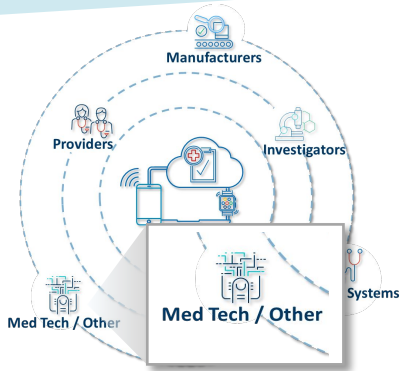
Artificial Intelligence (AI), Machine Learning (ML), and Real-world Evidence (RWE) is key and it can disrupt the way clinical studies are performed.

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: Med Tech / Other



Digital health data integration

- 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.



AI is needed to analyze and evaluate digital health information to be actionable for providers and patients

Using AI, devices can provide personalized insights/correlations based on the patient data.

Regulatory

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

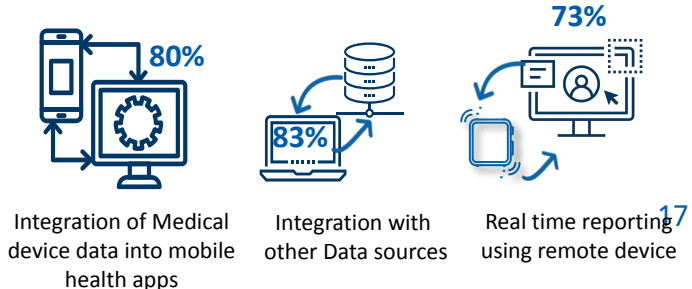
- Lack of Standards
- Understanding potential security risk
- Applying data security across Platforms

Patient access to data

66% of respondents believe that access to data has improved quality of care and 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 devices



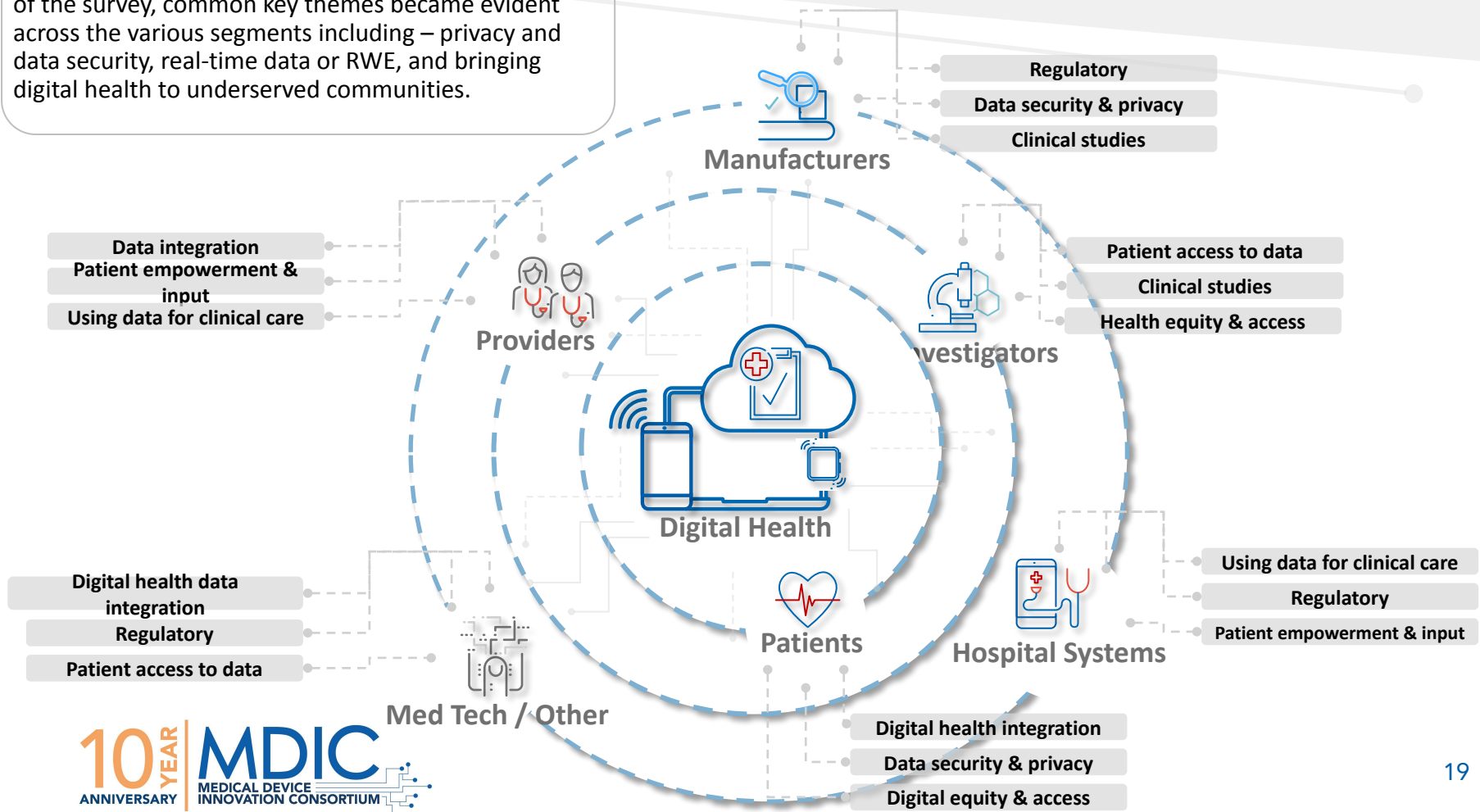
It is time for poll question #4:

Does your work (either research or product development) include patient-generated health data (PGHD)?

- Yes
- No

MDIC – Digital Health Survey: Summary output

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.





Industry Perspective

Heather Colvin



FDA CDRH
Perspective on Digital Health

Annie Saha

Thank You

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:

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Q&A Session

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Thank you

