

2016
DIGITAL HEALTH
SURVEY FOR
CONNECTED
MEDICAL
DEVICES

Digital
Medical
Communication
Roadmapping
Partnerships
Trends

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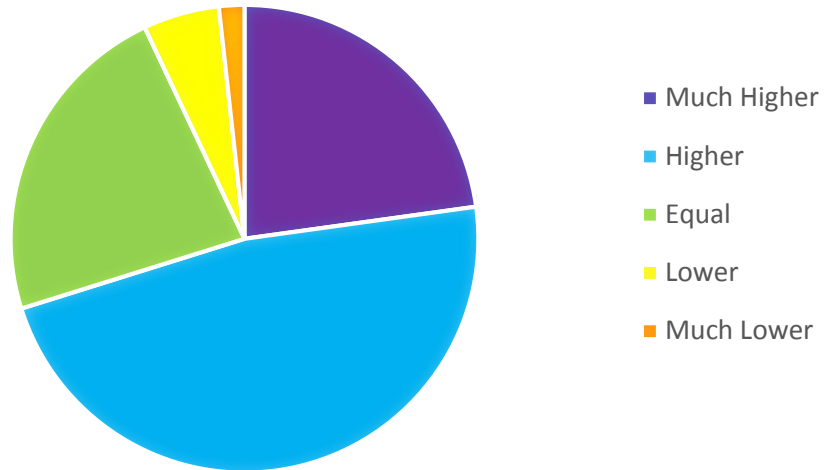
INTRODUCTION

StarFish Medical conducted a digital health survey of the North America medical device industry between March 3 and May 3 2016. The survey was promoted and distributed with communications assistance from Biocom, LifeSciences Washington, Medical Alley, Interface Health, MEDEC, MD+DI, and LifeSciences BC.

Participants who currently have medical device products with Digital Health connectivity or plans to introduce Digital Health connectivity for medical device products in 2016 were asked multiple choice and open ended questions using SurveyMonkey. Participants without Digital Health connected medical device products or 2016 plans were excused after submitting the reason(s) for lack of connected products or plans. Additional follow-up interviews were conducted with participants who provided contact information to clarify responses and provide anecdotal information when required.

This report summarizes the data and results of 15 questions. There were 148 respondents, of which 58 fully completed the survey. We believe the limited number of responses despite extensive promotion from industry associations and publications indicates the medical device industry is still in early stages of adopting Digital Health connectivity. The survey results should be viewed as qualitative information and not be used for quantitative extrapolation.

PRIORITY LEVEL OF DIGITAL HEALTH FOR 2016



Question: Is Digital Health a higher or lower priority for your products and services in 2016 than it was in 2015?

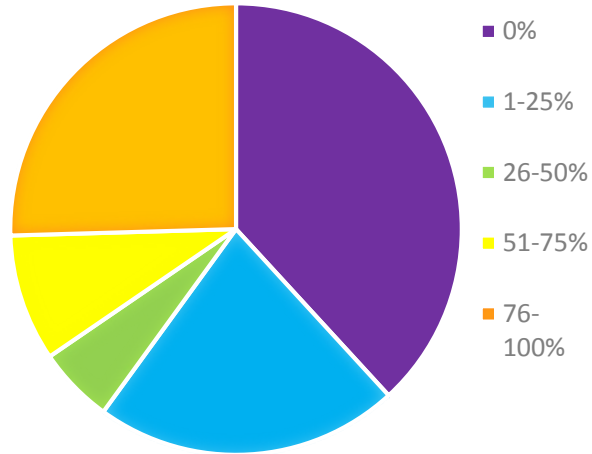
Write-in comments:

“Just investigating the use of blue-tooth enabling devices and diagnostics etc..”

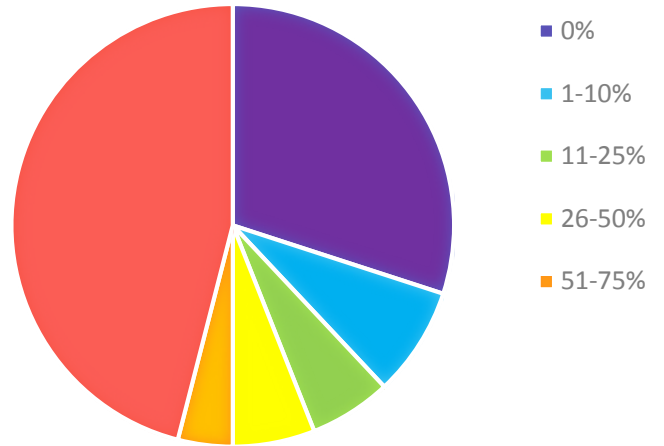
Conclusions:

Medical device product developers expect Digital Health to gain momentum in the coming years. Almost 75% of respondents claim it will be a higher priority in the future. [Numerous other studies](#) show a similar trend in the expected growth of the digital health market.

PERCENTAGE OF PRODUCTS CONTAINING DIGITAL HEALTH



PROTECTED HEALTH INFORMATION ON DIGITAL HEALTH PRODUCT



Question: What percentage of your products contain Digital Health connectivity?

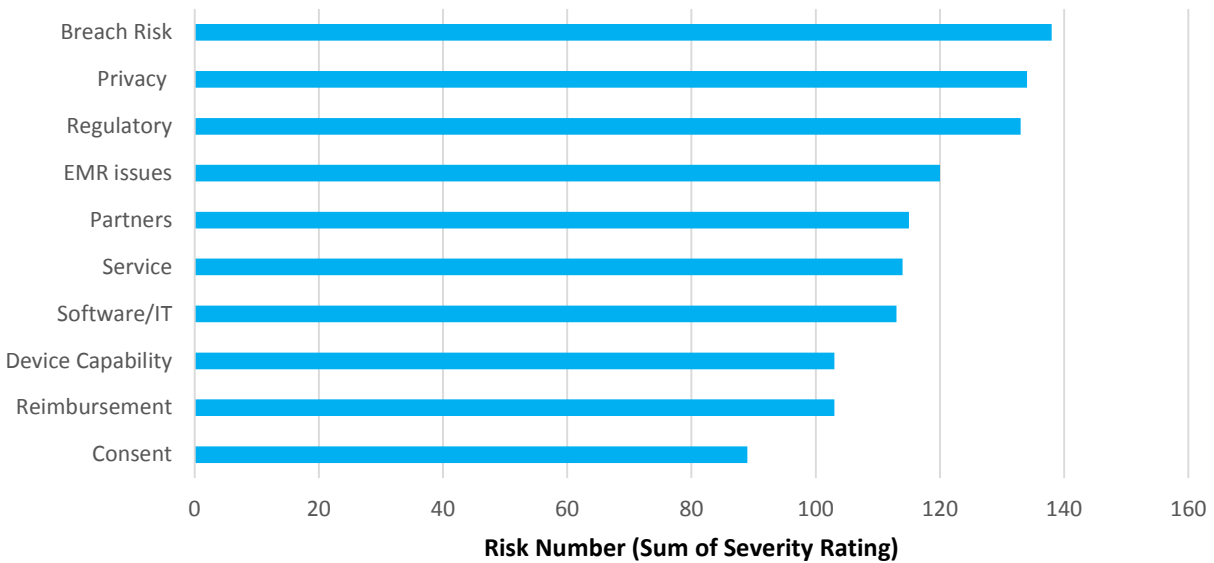
Write-In comment:

“Could not accurately state”

Conclusions:

A good share of respondents’ products currently contain Digital Health. More than half of those products contain Protected Health Information (PHI).

Ranking Perceived Digital Health Risks



Question: Are any of the following potential challenges impacting your success (as listed on left of chart)? (Scored each from 1-7 with 1 equal to 'No Impact' and 7 equal to 'Blocking').

Write-in comments:

“Not applicable to our device”

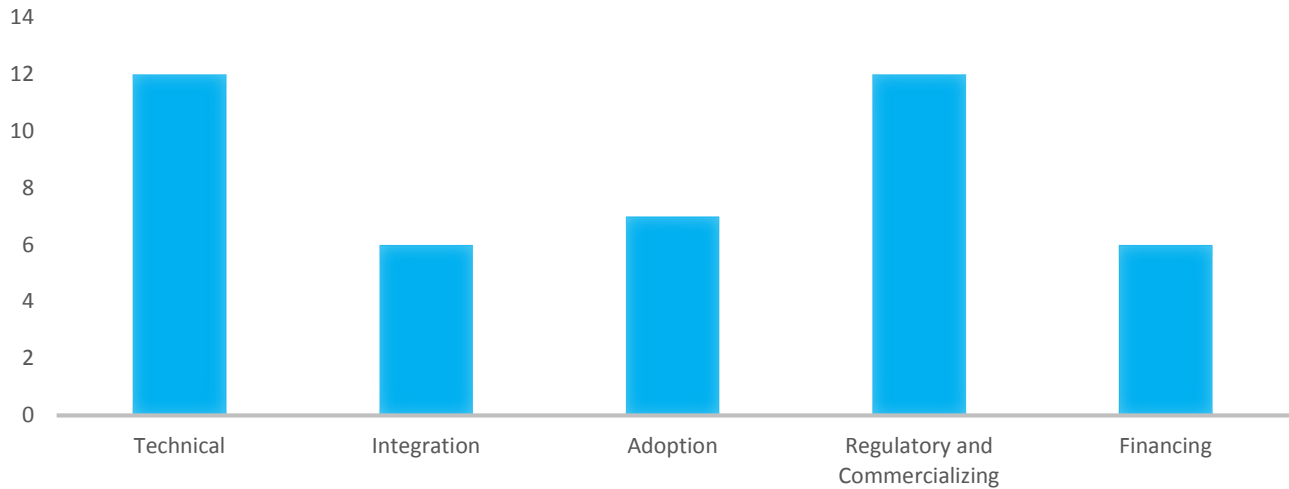
Conclusions:

Medical device makers with digital health connectivity rank Security, regulatory, and privacy as their most significant challenges. As StarFish Medical President, Scott Phillips, put it in his recent article, [The Biggest Challenges in Digital Health Product Development](#):

“In the age of WikiLeaks and the Panama Papers those are sensible concerns. We anticipate that some larger infrastructure providers will appear with time to offer digital health data management and security within standard and cost effective models”.

The next set of most challenging issues are related to interacting with other EMR and other partners and medical infrastructure. Service, reimbursement, technology, and consent are the least significant challenges.

CHALLENGES OVER THE NEXT 2 YEARS



Question: What is your biggest Digital Health challenge in the next 2 years?

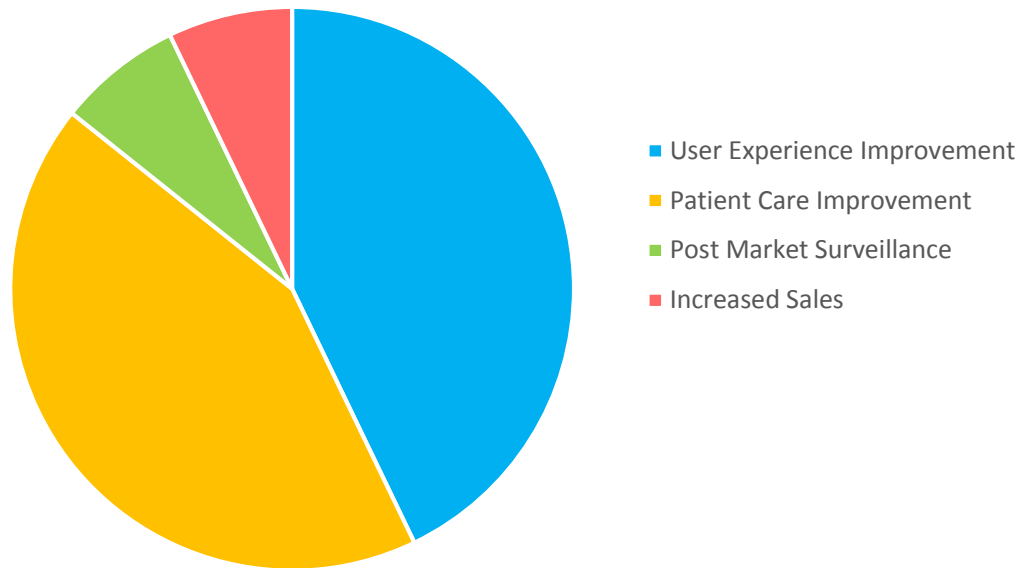
Some of the write-in responses:

Database management for large datasets, Design, testing, commercialization, New product conception, Regulatory compliance, user focus group consensus, Financing, Forming partnerships with physicians to develop devices, Increase robustness of offering and emr/ehr interface/integration, partnering, data logging and funding, Customer understanding and market place inertia

Conclusions:

Respondents were asked to write in their current and future Digital Health connectivity challenges. The responses were sorted for similarities and resulted in the above categories. Regulatory issues were the most significant challenge. Contrary to question responses elsewhere in the survey, integration was only mentioned by two respondents.

BENEFITS TO DIGITAL HEALTH



Question: What are the benefits and challenges from the project to date?

Sample of write-in comments:

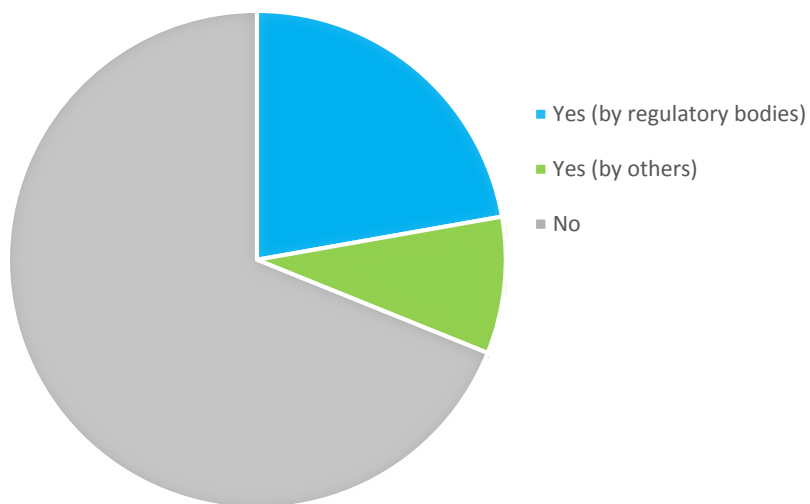
CHALLENGES: Finance, Acceptance of new and better techniques, challenges of moving through commercialization process, challenges: connectivity of BT, WiFi and cellular for device to table and tablet to server. Benefits: upload data to server for health care pro to review and for future analysis, patient compliance, effectivity of treatment

BENEFITS: R&D Study for new therapy technique: insights, improved practices for the healthtech industry, improved patient care, Enhance health outcomes and increased office efficiency, Exciting improvement to dosing and pt compliance / tracking

Conclusions:

Respondents were asked to write in the benefits Digital Health connectivity brings to their medical device. Again, responses were sorted by similarities and resulted in the above categories. Improving patient care (through user experience and patient improvement) were the most popular benefits (85%). Only 15% of responses identified improved business practices (post market surveillance and increased sales) as benefits.

SOFTWARE SYSTEM AUDITS



Question: Has your software system been audited?

Write-in comments:

No: "Planned for Future" or "In Progress"

Yes: "Outside software engineers and audit agencies"

Yes: "Privacy Impact Assessment"

Yes: "GMP"

Yes: "TUV"

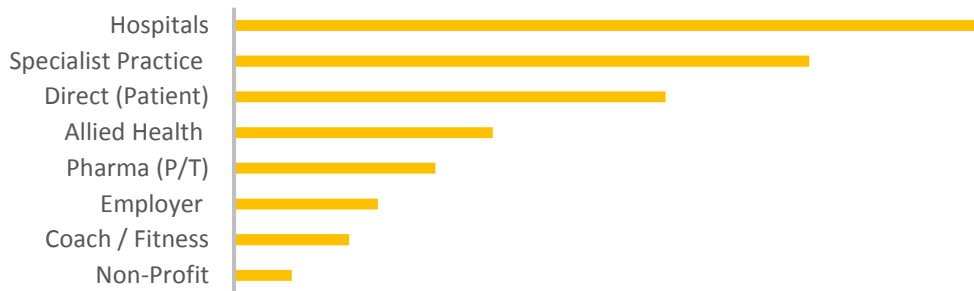
Many responders clarified that their audits are ISO 13485 and/or FDA and/or Health Canada

Yes: "SGS, Orion"

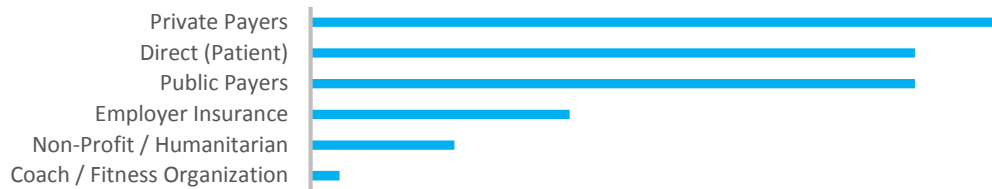
Conclusions:

Auditing software is not a common practice for respondents. Based on their write-in comments, this is likely related to devices being in early product development.

PURCHASE DECISIONS FOR DIGITAL HEALTH PRODUCTS



PAYER OF DIGITAL HEALTH PRODUCTS



Question: (1) Who makes the purchase decision for your Digital Health product(s), (2) Who actually pays for your Digital Health product(s)?

Purchase Write-in comments:

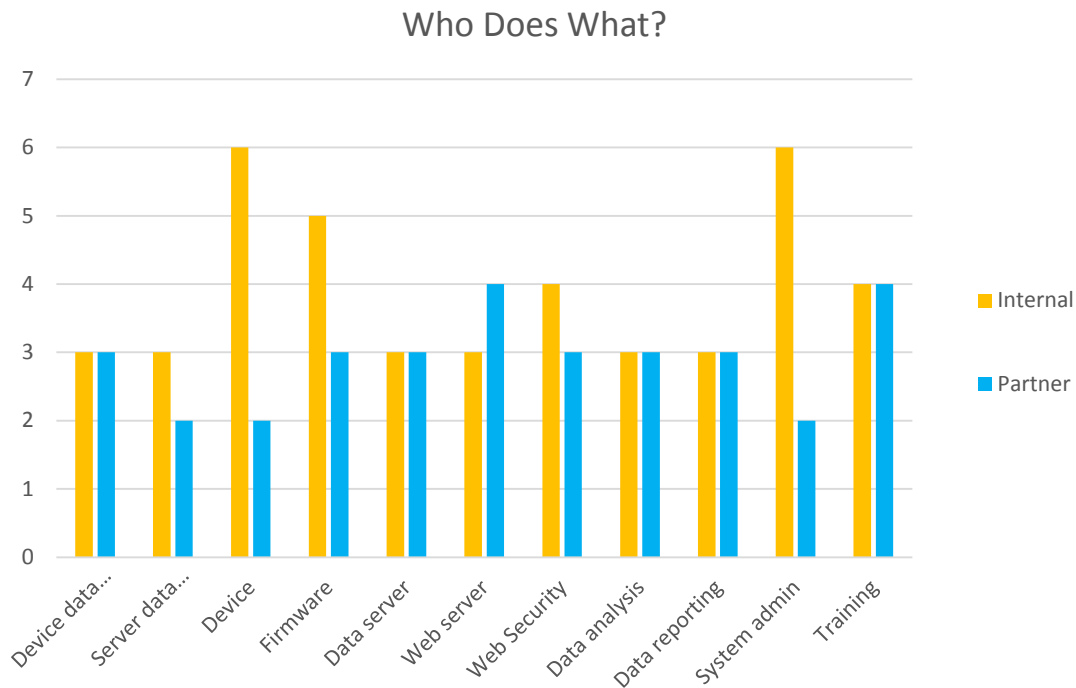
“To Be Determined, Physician, Interventional cardiologists who administer treatment during a heart attack, Like an Rx it requires an authorization, but patient pays all. Working with payers to reduce their costs in other parts of their system, Surgeons, Radiologists, Requires a physician prescription”

Sample Pay Write-in comment:

“Still working with CMS on reimbursement, to be determined, not applicable for our device, patient through clinic, family members”

Conclusions:

Hospitals and specialists are the most common purchasing groups, but the patient also makes up a significant demographic. Employers, fitness and non-profit are the least common. Private and public payers, and patients pay for the majority of the devices. Employer insurance, non-profit and fitness organizations are the least common payers.



Question: Who handles the following for your software system infrastructure?

(Note: only respondents that had a software audit were included in these results)

Write-in comments:

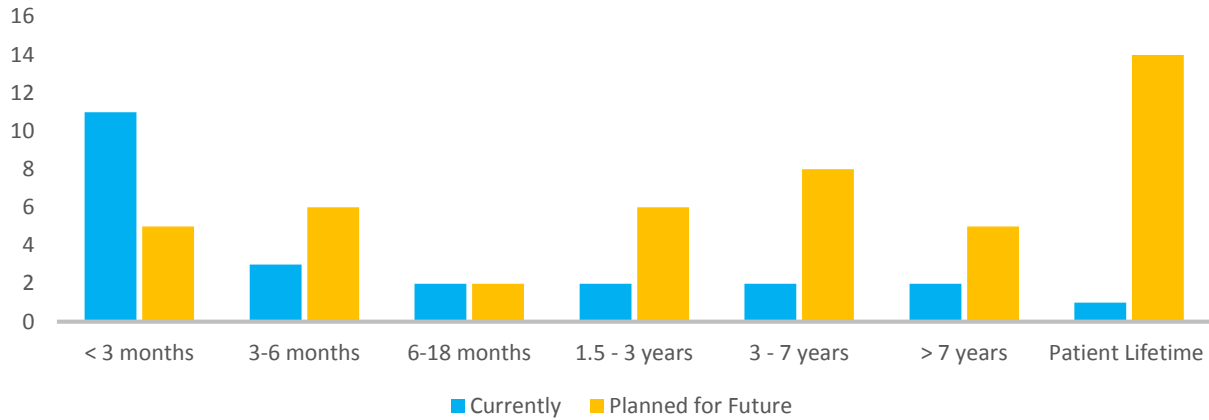
“In process”

“Unsure at this time”

Conclusions:

Partners are utilized for many different roles in the software infrastructure. There is roughly a 50/50 split between outsourced and internal responsibilities for all roles except the device itself, the firmware, and the systems administration.

LENGTH OF CONTINUOUS DATA SETS



Question: What is the longest continuous data set you maintain with your Digital Health solution?

Write-in comments:

“In process”

“Unsure at this time”

“We keep all raw data in the cloud in perpetuity 300,000 plus readings and counting...”

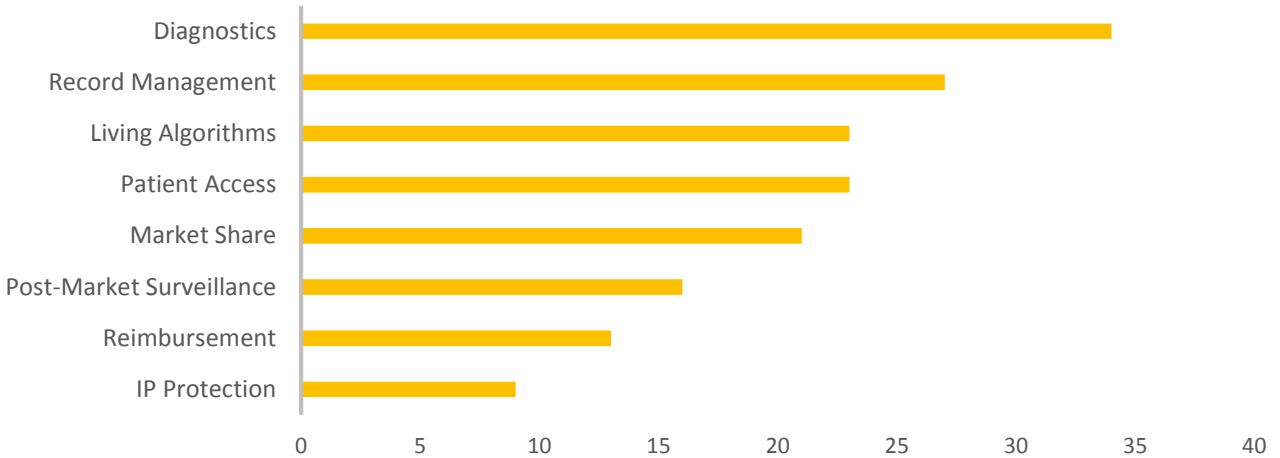
“Plan to provide data for patients for life of the organization with opportunity to access and download data for one year following any cessation of operations.”

“Not Applicable”

Conclusions:

Few existing systems maintain long continuous data sets. Products may simply not be in use long enough to build long continuous data sets. Or this might indicate a trend towards embedded health care for all types of people. Devices for patient lifetime are planned to be the largest single group of medical devices.

WHY INCLUDE DIGITAL HEALTH CONNECTIVITY?



Question: Why do you include (or plan to include) Digital Health connectivity in your devices? Please choose all that apply.

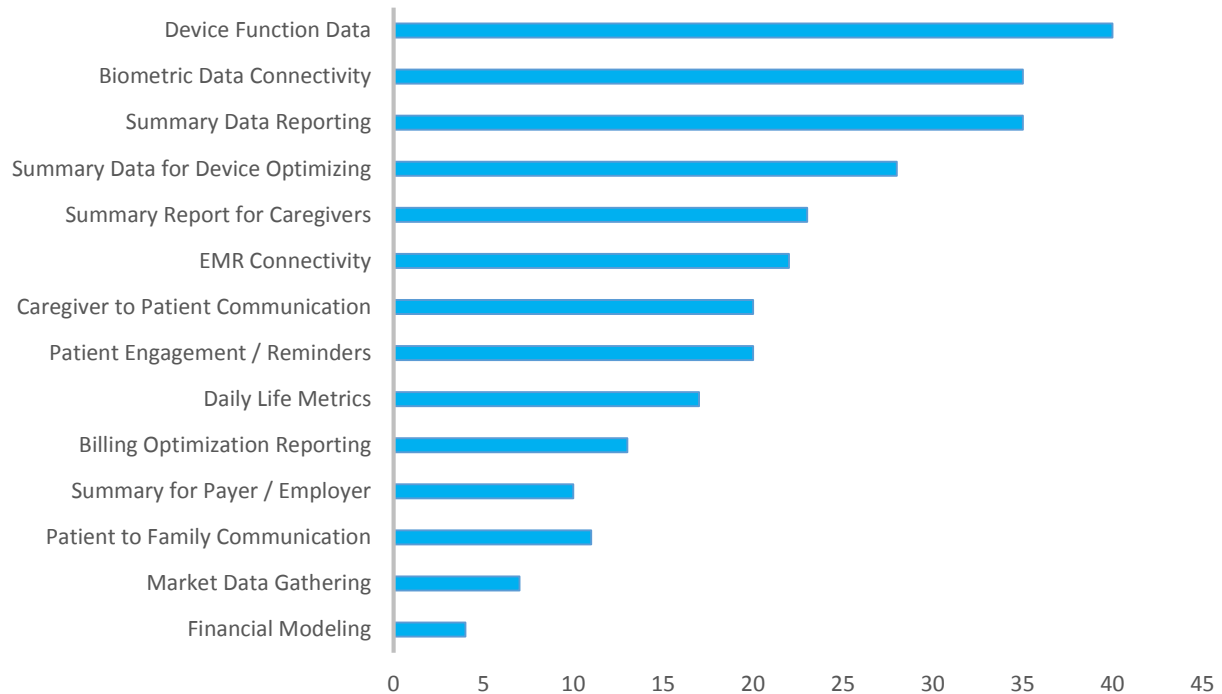
Write-in comments:

“Lower overhead and fewer errors to acquire data, Not applicable to our device, too early in product life cycle to consider, compliance, Market needs “Ongoing”, Connected health is the future, Physician control over home treatment.”

Conclusions:

Diagnostics and Record Management are the two most cited reasons for including Digital Health connectivity in devices. IP protection and reimbursement were the two least cited.

WHAT FEATURES DOES YOUR DEVICE INCLUDE?



Write-in Comments:

“Cinic and Partner Workflows”

“EMR interoperability layer, Doctor dashboards and engagement platforms, CMS billing support”

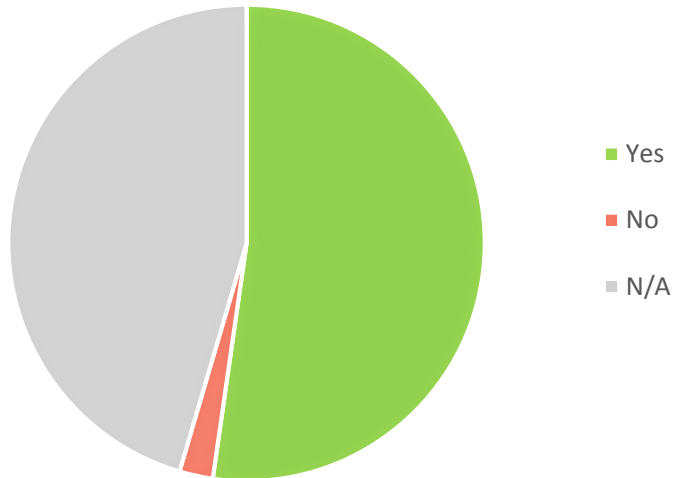
“Image viewing / interpretation by multiple clinicians (PACS / DICOM integration)”

Conclusions:

Much like the cited reasons for digital health features, market data gathering was near the bottom. Device functionality and summary data for device optimizing were near the top. Record management scored highly in the previous graph, but EMR connectivity scored much lower in this question.

There is a higher priority to get the data to the caregiver for interpretation (reducing device risk) than to create summaries for other parties such as payers or family. Interestingly, financial features score near the bottom again.

WAS YOUR DIGITAL HEALTH PROJECT SUCCESSFUL?



Question: Was your Digital Health connected project(s) successful?

Write-in Comments:

"Has been and continues to be... touch wood."

"Not yet"

"Some were, some weren't"

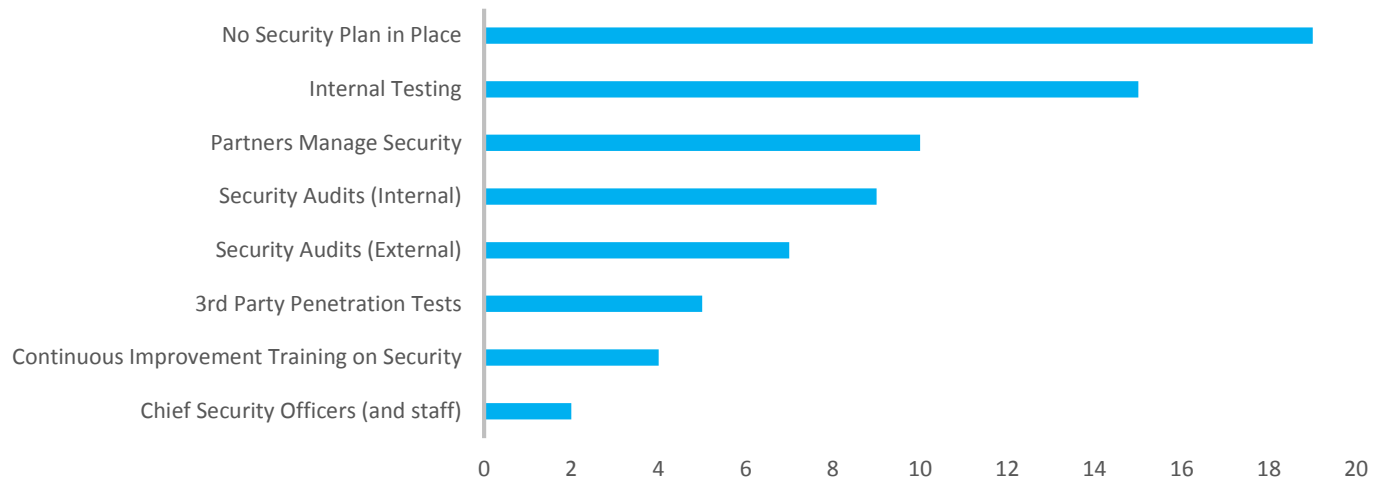
"Ongoing"

"Not currently on the market"

Conclusions:

Either only a small sliver of digital health products were unsuccessful or respondents did not want to identify their failures in the survey. Based on previous answers it may also mean that many devices are still in development.

MONITORING SECURITY



Question: How do you monitor security?

Write-in comments:

“In process, have board members with significant digital security background”

“Don't know, not really involved with that area”

“Have not started this yet”

“Not applicable to our device”

Conclusions:

Most of the participating developers do not have a security plan in place. Many of those that do have a plan use internal resources for testing.

CONCLUSIONS:

Digital Health connectivity and functionality is a growing trend for medical devices. Most device developers responding to this survey are including Digital Health functionality to enhance the performance of their diagnostic devices rather than for other benefits such as billing or post market surveillance. These connected devices are in use for periods ranging from short term (less than 2 months) to long term (patient lifetime). Most devices are being marketed to hospitals, practitioners or consumers, with the narrow majority being billed to private payers followed by consumer payers.

The survey provides readers useful information on:

- 1) Current and future challenges involved in developing a medical device with Digital Health functionality
- 2) Common features of connected medical devices and the purpose of those features
- 3) Partnerships and available 3rd party resources. Each is critical in understanding the path to success for digital health connected medical device development and each is also related to the growth potential of the market.

The survey also shows that security is a major concern for developers but isn't commanding a lot of effort early in the design phase. The majority of respondent devices do not have a security plan in place and most of their devices have never had a software audit. These are all indicators of early phase Digital Health products which are not yet in the market.

Based upon survey responses, the state of the Digital Health market is strong and growing. We hope the information in this survey helps enable decisions and promotes development for Digital Health connected medical devices.

StarFish Medical appreciates the input of all those who contributed to the survey. We thank Biocom, LifeSciences Washington, Medical Alley, Interface Health, MEDEC, MD+DI, and LifeSciences BC for their promotion of the survey to members and readers of their respective publications. We welcome feedback and are happy to discuss this report or share details from the survey with participants and readers.



Scott Phillips

Additional free materials and advice
to help commercialize your medical device concept:

Product Development Sanity Check: 50 questions to improve your medical device concept
<http://starfishmedical.com/assets/Pathfinder-Checklist-Medical-Device-Review.pdf>

Human Factors Guide & Checklist – Improve Your Usability Engineering
http://starfishmedical.com/assets/Usability-Engineering-Framework_2014.pdf

Medical Device Regulatory Checklist
http://starfishmedical.com/assets/Regulatory-Checklist_Starfish_2014-FINAL.pdf

Free 1 Hour Consultation on Commercializing Your Medical Device
<http://starfishmedical.com/no-obligation-commercialization-consultation/>

Medical Device Basics Video Series

Understanding The Root Problem
<https://www.youtube.com/watch?v=sYNsJYI--W0>

The True Value of Clinical Input
<https://www.youtube.com/watch?v=xVWhDhPuYig>

Developing Value Chains and Margins
<https://www.youtube.com/watch?v=23jHF54jfgE>

Determining Your Technology Readiness
<https://www.youtube.com/watch?v=QPqXcWJTdtM&feature=youtu.be>

Complying with Standards
<https://www.youtube.com/watch?v=xaM5y8pDhPU>

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Our proprietary Pathfinder process for medical device product definition saves clients time and resources throughout technical engineering and product development. Prototype and low volume production are delivered in an ISO 13485 certified facility with FDA registration and clean room capabilities.

Our ISO 13485 consultants provide technical regulatory assistance for FDA and Health Canada submissions including IEC 60601. StarFish Medical QMS-in-a-Box solutions ensure an effective and affordable Quality Management System that establishes a clear commitment to medical device regulatory compliance for development and independent client companies.

