PTC AND KALYPSO PRESENT:
AN AXENDIA MEDICAL DEVICE RESEARCH SURVEY

THE IMPACT OF IOMT ON PATIENT OUTCOMES:
CHANGING THE BUSINESS OF HEALTHCARE IN
THE OUTCOME ECONOMY

© 2018 Axendia, Inc.
IMPROVING THE BUSINESS OF HEALTHCARE IN THE OUTCOME ECONOMY

The delivery of modern healthcare has become increasingly reliant on sophisticated medical devices, technologies and facilities. Historically, healthcare has been episodic and reactive — primarily aimed at addressing a malady, illness or injury after it has already happened.

As soon as patients are admitted to a hospital, they are connected to a plethora of medical devices supported by a wide range of diagnostic, surgical and therapeutic systems. These in turn depend on complex facilities, health information technologies and related IT infrastructures.

This reactive approach is expensive and unsustainable. As a result the healthcare ecosystem is looking for ways to transition from reactive care to preventive and outcome based healthcare models.

The Internet of Medical Things (IoMT) can enable the transition to patient-centered preventive care. The use of IoMT connected devices will play an important role in supporting improved quality of care, patient outcomes and improve the business of healthcare in the outcome economy.
Internet of Things (IoT) will have a major impact on the “Business of Healthcare.” 83% of participants in Axendia’s survey using smart and connected devices expect to increasingly participate in more interconnected health networks as a result of IoT initiatives.

IoT is fostering connections among a variety of devices including biometric sensors on personal wearable devices like wristbands and watches (e.g., Apple watch, Fitbit, and Microsoft band); at-home devices like connected scales, thermometers, glucose meters, and blood pressure monitors; and connected implantable devices like EKG’s and even at-home kidney dialysis machines. These connected health devices are evolving into the Internet of Medical Things (IoMT). IoMT connected devices can send health information to caregivers, clinicians or a multitude of other remote patient monitoring technologies that proactively alert caregivers to problems.

42% of research participants expect that IoMT will fulfill the promise of personalized patient care through individualized monitoring and care plans in the next 5 years.

© 2018 Axendia, Inc.

**SURVEY RESULTS**

**IoMT WILL CHANGE THE BUSINESS OF HEALTHCARE**

How do you expect your business will change over the next 5 years from IoT initiatives?

(Respondents completed the sentence “We will increasingly...”)

- ...participate in more interconnected health care networks 83%
- ...link to networked data and analytics in products 58%
- ...rely on sensors to improve up-time and schedule preventative maintenance 42%
- ...fulfill the promise of personalized patient care through individualized monitoring and care plans 42%

6 OUT OF 10 research participants using smart and connected devices expect they will increasingly link to networked data and analytic in products. IoMT connected devices will improve patient care by providing the health care industry with better aggregated information to continually improve products and services.
Technology is entering medical practice at an increasing and accelerated rate. The proliferation of medical technology has created a strain on capital investment and operating budgets for healthcare providers and caregivers.

As a result, providers and medical device manufacturers are implementing outcome based models, shifting from asset acquisition to fee-for-outcome.

To support outcome based models, manufacturers of imaging and diagnostic equipment, such as X-ray, CT, MRI, molecular imaging and ultrasound, are beginning to shift from selling capital equipment like diagnostic and imaging machines to selling images, studies and tests to improve outcomes.

In the outcome based economy, the device manufacturer:

- Owns the asset and thus the responsibility for maintaining it in running order
- Actively monitors the performance of the asset
- Maintains and repairs the assets and provides the people, facilities and tools needed to perform maintenance and repair
- Charges customer per outcome of use

Using IoT, manufacturers are creating new business and service models. In this new model, the manufacturer is responsible for equipment uptime based on a service level agreement. This contract drives them to use IoMT to prevent issues before they happen, improve equipment uptime and performance, as well as find new ways to extend asset longevity by managing these assets more efficiently and effectively. This allows for a shift from reactive/break-fix, to proactive and predictive maintenance models.

The use of smart and connected technologies in diagnostic devices plays a key role in the transition from purchasing equipment to purchasing outcomes (studies). Over 40% of those using smart and connected devices expect they will increasingly rely on sensors to improve up-time and schedule preventative maintenance.

How do you expect your business will change over the next 5 years from IoT initiatives? (Respondents completed the sentence “We will increasingly...”)

- participate in more interconnected health care networks [83%]
- link to networked data and analytics in products [58%]
- rely on sensors to improve up-time and schedule preventative maintenance [42%]
- fulfill the promise of personalized patient care through individualized monitoring and care plans [42%]
- participate in initiatives to deliver patient care remotely [33%]
- leverage anonymized, aggregated data in research initiatives [33%]
- sell healthcare outcomes as a service [25%]
- Other (please specify) [8%]
Realizing the benefits of IoMT requires overcoming some key challenges. Connected devices can present security challenges that left unmitigated could pose serious risk across the healthcare ecosystem and negatively impact the patient.

When asked about the biggest challenges faced in bringing smart, connected products to market, “device and data security” and “interoperability with healthcare networks and systems of record” were the top response (50%). “Privacy of patient data” and “delays due to regulatory oversight” were also a key challenges (33%).
Cybersecurity for medical devices and healthcare data are not optional. In fact, in its *Postmarket Management of Cybersecurity in Medical Devices* guidance, FDA emphasizes that "manufacturers should monitor, identify, and address cybersecurity vulnerabilities and exploits as part of their postmarket management of medical devices."

Furthermore, the guidance encourages collaboration among healthcare delivery organizations, the clinical user community, and the medical device community to drive the consistent assessment and mitigation of cybersecurity threats and vulnerabilities, and their impact on medical devices, ultimately reducing potential risk of patient harm.

**SURVEY RESULTS**

**IoMT SECURITY CHALLENGES**

<table>
<thead>
<tr>
<th>CHALLENGES</th>
<th>WHAT YOU NEED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>COMPLEXITY</strong></td>
<td>New layer of device and user interactions need to be secured</td>
</tr>
<tr>
<td></td>
<td>Extremely flexible permissions and visibility capability</td>
</tr>
<tr>
<td><strong>RISK MITIGATION</strong></td>
<td>Concerns over cyber attacks finding devices on the internet</td>
</tr>
<tr>
<td></td>
<td>Device-initiated communication provides single method of IoMT system connection</td>
</tr>
<tr>
<td><strong>PATCHES</strong></td>
<td>Inability to easily provide security updates to devices</td>
</tr>
<tr>
<td></td>
<td>Infrastructure to manage, control and distribute security patches</td>
</tr>
</tbody>
</table>
As the large volume of data from IoMT connected devices is correlated with other datasets across the total product lifecycle (TPLC), manufacturers will be able to “close the loop”, from design to field service. In fact, 80% of respondents using IoT connected devices report that the biggest benefit of closing the loop is providing engineering teams with real time visibility into post-production quality and performance information.

Closing the loop with IoMT also enables medical device manufacturers to turn connected product data into meaningful business value. 80% of respondents using IoT connected devices report that they see reducing the cost of poor quality as a key benefit.

Closing the loop through IoMT can help medical device manufacturers realize a higher level of customer service and internal operational efficiency as well as delivering value-added services to meet caregiver and patient needs.

**SURVEY RESULTS**

**IoMT CLOSES THE HEALTHCARE LOOP**

What are the biggest benefits of “closing the loop” between quality processes and the rest of the product lifecycle? (Respondents selected top three)

<table>
<thead>
<tr>
<th>Benefit</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce the cost of poor quality</td>
<td>80%</td>
</tr>
<tr>
<td>Provide engineering teams with real-time visibility into post-production quality and performance</td>
<td>80%</td>
</tr>
<tr>
<td>More rapid response to quality issues</td>
<td>50%</td>
</tr>
</tbody>
</table>

© 2018 Axendia, Inc.
A high-tech approach to healthcare is already happening. Wearables, for example, provide patients with chronic conditions the ability to interact with their practitioners and caregivers sooner.

IoMT is also enabling the transition from episodic care to a proactive and outcome based healthcare model. When asked “What are the biggest patient benefits of smart, connected devices?” over 60% of survey participants responded: “Improved outcomes through continuous monitoring and escalation procedures.”

IoMT connected devices provide incredible opportunities to bring insights and capabilities to healthcare in an automated way to benefit patients and health systems. Over 50% of respondents expect that smart and connected devices will provide more accurate, fact-based diagnoses, through improved analytics. In fact 2 out of 3 manufacturers of diagnostic devices report IoMT as the biggest industry disruptor.

**What are the biggest patient benefits of smart connected devices?**
(Respondents selected top three)

- Improved outcomes through continuous monitoring and escalation procedures: 60%
- More accurate, fact-based diagnoses, through improved analytics: 51%
- Improved access to health metrics via smartphone or tablet: 31%
- Reduced health care costs through remote service delivery: 31%
- Improved access to healthcare providers in remote and rural locations: 30%
- Other: 11%
The healthcare ecosystem is transitioning from a reactive to proactive provider of services. IoMT is providing the conduit for connecting devices and information from manufacturer to provider to patient.

Today, IoMT connected medical devices are providing measurements that can be analyzed to prevent ailments or actively manage chronic conditions. Outcomes now can be measured by the overall health and wellness of individuals in particular, and the population in general.

Realizing the benefits of IoMT requires overcoming some key security challenges that left unmitigated could pose serious risk across the healthcare ecosystem and negatively impact the patient.

As healthcare constituents continue to move from a fee for service to a fee for outcome model, the IoMT is enabling the transition to patient centered preventive care. The use of IoMT connected devices will continue to play an important role enabling more interconnected health networks that support improved prevention, quality of care, healthier outcomes and change the business of healthcare in the outcome economy.

© 2018 Axendia, Inc.
ACKNOWLEDGEMENTS

This white paper was written by Axendia, Inc. The opinions and analysis expressed in this research reflect the judgment of Axendia at the time of publication and are subject to change without notice. Information contained in this document is current as of publication date. Information cited is not warranted by Axendia but has been obtained through a valid research methodology. This document is not intended to endorse any company or product and should not be attributed as such.

About Axendia:

Axendia, Inc. is a leading trusted advisor to the Life-Science and Healthcare industries. We provide trusted counsel to industry stakeholders on Business, Regulatory and Technology issues. We are honored to be recognized by CIOReview as a one of the 20 Most Promising Life Sciences Technology and Services providers.

For more information, visit www.axendia.com or contact us at info@axendia.com
Read Axendia’s blog: Life-Science Panorama at http://LSP.axendia.com
Follow us on Twitter at twitter.com/axendia
Follow us on LinkedIn at linkedin.com/company/axendia-inc.

The following members of Axendia contributed to the development of this white paper series.

Daniel R. Matlis  President
Monica V. Matlis  Vice President
Ellyn McMullin  Research Associate
Sandra K. Rodriguez  Market Analyst

Axendia conducted a study focusing on the future of smart, connected devices and how the medical device industry perceives the impact of the Internet of Things (IoT) on patient outcomes. In support of the research, we surveyed 110 medical device professionals to identify and analyze trends and requirements in support of IoMT initiatives and bringing smart, connected products to market.

This illustrated guide has been developed based on the outcomes of the survey and interviews with industry thought leaders. In it, we discuss the value, challenges and opportunities to change the business of healthcare in the outcome economy.