



# Executive summary

Medical technology (MedTech) companies are facing new realities, expectations, and success measures in today's dynamic cardiovascular disease (CVD) market. A confluence of five trends—increasing demand for value, uptake of innovative treatment technologies, growing adoption of digital solutions, changing MedTech competitive landscape, and evolving provider and care delivery shifts—is generating greater scrutiny of MedTech CVD offerings and heightening requirements for MedTech companies to succeed. Now, more than ever, it is critical that MedTech organizations get to the heart of the changes taking place in the CVD ecosystem; reexamine how best to engage with patients, providers, payers, emerging competitors, and other stakeholders; and assess which strategies they should pursue to position their organizations for success in CVD. Leadership teams seeking a competitive advantage should begin by addressing the following questions:

- Given your existing solutions portfolio, should your organization adopt a mindset of incremental or transformational change?
- Where are the new business opportunities, and what role do you want to play in transforming care delivery models in cardiovascular? What will be your basis of competition in this new reality?
- To what extent do you need to rethink your go-to-market model and customer engagement mechanisms as the cardiovascular market shifts?
- How will your product development approach be impacted by this new reality? Are there alternative models or external collaborations to consider?
- What is the end-to-end “readiness” view of your organization so you don't just survive, but thrive, in this new reality? What capabilities should you strengthen and how should you invest?
- How should you align and adapt your corporate culture to better prepare for a CVD future that may look very different than today's?

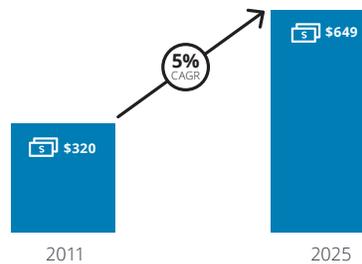
# Understanding the changing cardiovascular market

**i Cardiovascular disease (CVD),** or heart disease, is an umbrella term that includes all conditions affecting the heart. It refers to conditions that can lead to chest pain, heart attacks, strokes, and other related conditions. Examples include coronary artery disease, arrhythmias, and heart defects, among others.

Heart disease is the leading cause of death in the United States, affecting about 600,000 people each year.<sup>1</sup> More than 85 million Americans are living with some form of cardiovascular disease or stroke,<sup>2</sup> and by 2030, more than 40 percent of the US population is expected to have some form of CVD,<sup>3</sup> a prevalence increase of 10 percent.<sup>4</sup> In addition to the rising prevalence of CVD, there is a rise in comorbidities, which include diabetes, chronic pain, arrhythmias, and depression, and are more prevalent in the elderly Medicare populations.<sup>5</sup>

Given the anticipated uptick in CVD, comorbidities, and associated diagnosis and treatment, the financial burden of CVD also is expected to grow, with the estimated direct cost of CVD in the US doubling from 2011 to 2025, an increase from \$320 billion to nearly \$649 billion (Figure 1).<sup>6</sup> The market for CVD products is also expected to grow due to increasing prevalence of CVD.

Figure 1. Estimated direct cost of CVD in US (\$B 2011)

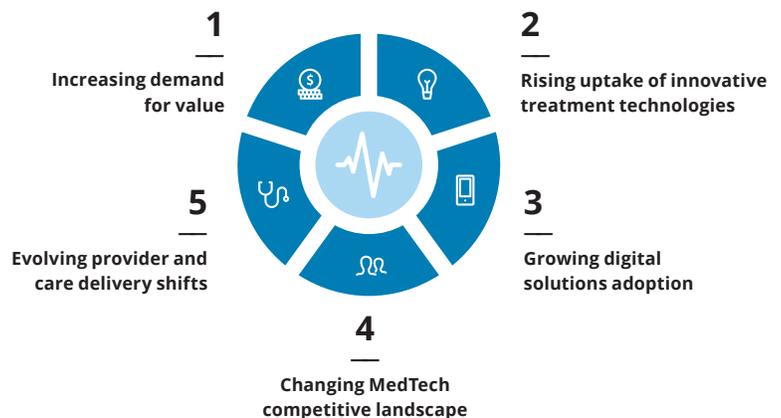


The direct cost of CVD is expected to **double** from 2011 to 2025

## Five market trends reshaping the CVD market

Five broad health care trends are reshaping the CVD market, directly and indirectly impacting MedTech companies and their customers (Figure 2). Now, more than ever, MedTech organizations need to get to the heart of the changes taking place; reexamine how best to engage with patients, providers, payers, emerging competitors, and other stakeholders; and assess which strategies they should pursue to position their organizations for success in CVD.

Figure 2. Five market trends impacting the cardiovascular landscape



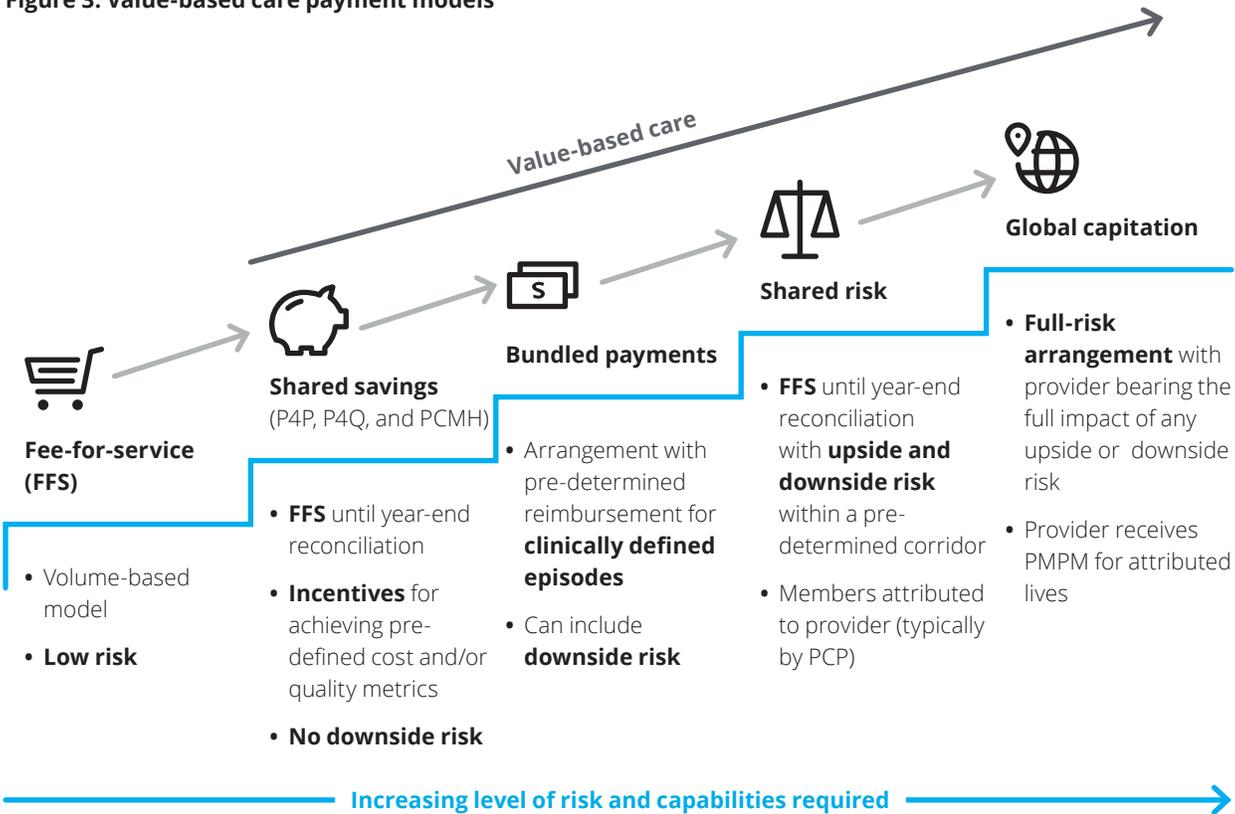


# 1

## Increasing demand for value

US health care's shift from volume-based, fee-for-service (FFS) payment models to those focused on quality and patient outcomes extends to cardiovascular care. Value-based care (VBC) payment models exist on a continuum, with increasing levels of risk and required capabilities (Figure 3).

**Figure 3. Value-based care payment models**



Shared savings programs include pay-for-performance (P4P), pay-for-quality (P4Q), and patient-centered medical homes (PCMHs). These models have no downside risk by using the FFS model until year-end reconciliation, and offer incentives for achieving pre-defined cost and/or quality metrics. Currently, the US Centers for Medicare and Medicaid Services (CMS) is offering incentives based on utilization of post-cardiac care services by patients recently discharged.<sup>7</sup>

Bundled payment programs are arranged on a pre-determined reimbursement for clinically defined episodes, and can include downside risk for the provider. For example, in July 2016, CMS proposed a five-year demonstration project that would require hospitals in 98 metropolitan areas be financially accountable for the cost and quality of all care associated with bypass surgery and heart attacks.<sup>8</sup>

At the far side of the VBC continuum, global capitation is a full-risk arrangement with the provider bearing the entire impact of any upside or downside risk. The provider receives a per-member-per-month (PMPM) payment for attributed lives. Iora Health's capitated model resulted in a readmission rate for chronic CV patients between three percent and six percent, compared to a 16 percent readmission rate for Medicare.<sup>9</sup>

The shift to VBC is changing provider economics, placing MedTech manufacturers under a commoditization threat unless they deliver differentiated, high-impact solutions. Effectively competing in a VBC world requires that organizations focus on strengthening the following six winning capabilities—whether internally or externally through collaborations.

- 1. Deep understanding of care delivery models:** Understanding how care is—and will be—delivered for a specific disease or condition across patient populations to identify high-value, unmet needs and create robust value propositions for offerings.
- 2. Outcomes measurement and end-to-end evidence:** Constructing partnerships for data creation, capture, sharing, and analytics to assess real-world evidence (RWE) and demonstrate value (beyond traditional safety and efficacy) to support providers as they take on risk and are measured against each other.
- 3. Stakeholder engagement and collaboration:** Developing organizational capabilities to identify, create, and service new ecosystem relationships including accounts, stakeholders (inclusive of consumers, caregivers, and new influencers), and next-generation innovations.
- 4. Contracting and payment models:** Underwriting, negotiating, and implementing new payment models with payers, providers, and non-traditional entrants to account for value added to the different stakeholders and ecosystem.
- 5. Complementary services and solutions:** Building wraparound services or solutions that supplement clinical efficacy, address value leakage, and/or improve operational efficiency throughout the patient journey and care delivery continuum.
- 6. Product innovation:** Redefining innovation models to rapidly translate clinical and real-world insights into product offerings that clearly deliver superior system value, while also aligning regulatory strategy with overall evidence planning.

MedTech players are responding with solutions that leverage these capabilities, some on their own and others in collaboration with other stakeholders. For example:

- **Stakeholder engagement collaboration:** Philips and Banner Health partnered to identify and deliver connected health care solutions that improve patients' health in areas such as cardiology, while lowering costs and improving quality.<sup>10</sup>
- **Contracting and payment models:** St. Jude offers a 45 percent rebate for a Quadra heart rhythm device if revision surgery is needed within one year of implementation.<sup>11</sup>
- **Complementary services and solutions:** GE Healthcare's Global Services help health systems determine an optimal mix of clinical equipment to help lower costs.<sup>12</sup>
- **Product innovation:** Medtronic's Reveal LINQ™ implantable device with three-year continuous monitoring can detect heart arrhythmias or atrial fibrillations to prevent a second stroke.<sup>13,14</sup>

## Suggested steps for MedTech

The shift to VBC payment models is changing cardiovascular providers' economics and placing MedTech manufacturers under threat of commoditization unless they deliver differentiated, high-impact solutions. Demonstrating product performance is not enough; MedTech companies need to provide evidence that their cardiovascular solutions possess both clinical and economic value and support new financial arrangements and incentives for providers.



## 2

# Rising uptake of innovative treatment technologies

Innovative treatment technologies in CVD, such as transcatheter aortic valve replacement (TAVR) and 3D printing, are expanding the market for MedTech manufacturers.

TAVR enables less-invasive treatment options, which may reduce hospital stays, positively impact patients, and improve health care system efficiency. TAVR is used to treat patients with severe aortic stenosis (AS) whose traditional treatment options include medication for mild cases or open heart-surgery.<sup>15</sup> TAVR is also considered a viable treatment alternative for high-risk or older patients with other comorbidities who are ineligible for traditional valve replacement.<sup>16</sup> The rising incidence of AS cases, from 3.3 million in 2015 to 4.6 million by 2025,<sup>17</sup> growing payee acceptance and reimbursement of TAVR (two new diagnosis-related groups [DRGs] and 15 percent increase in average reimbursement),<sup>18</sup> and the expansion of approved indications for TAVR<sup>19</sup> indicates a growing market. As a result, TAVR is expanding the treatable patient pool and could potentially replace surgical AVR as the standard of care.<sup>20</sup>

Along similar lines, 3D printing is gaining increasing popularity in CVD treatment and has the potential to be used for disease prevention. Over the next five years, global revenue from 3D printing in medical devices is expected to triple, from \$0.8 billion in 2015 to \$2.4

billion in 2020.<sup>21</sup> In 2016, the average cost of a 3D printer was \$100,000, making it affordable for large- and medium-sized hospitals routinely performing surgical interventions. As of 2016, 75 US hospitals had installed 3D printers, with several others entering into contracts with 3D-printing firms.<sup>22</sup> It should be noted that many of these applications are experimental and not yet eligible for reimbursement.

There are several use cases for cardiovascular 3D printing:

- 3D-printed heart valves are being made from living tissue, which eliminates the need for prosthetic valves for aortic valve disease. Unlike prosthetic valves, these printed valves grow with the patient, providing benefits for growing children and young adults.<sup>23</sup>
- Clinicians are creating a 3D-printed model of an actual patient's heart and performing mock surgery on it to fine tune their approach. This provides less-risky surgeries for patients and will likely improve outcomes.<sup>24</sup>
- 3D printing can be used as a tool to identify suitable candidates for valve implantation. It can be beneficial for patient selection for procedures as well as for research purposes.<sup>25</sup>

### Suggested steps for MedTech

The uptake of innovative treatment technologies, including TAVR and 3D printing, is creating new cardiovascular treatment options and expanding the MedTech CVD market. Providers are interested in—and MedTech companies should develop and offer—a wide spectrum of diagnostic, therapeutic, and monitoring solutions that providers can leverage to manage the patient journey—enabled by the right technology, supported by evidence and a strong value proposition, and available at the right time.



# 3

## Growing digital solutions adoption

There is emerging evidence that some CVD programs built around digital solutions have resulted in benefits to both patients and providers. A 2015 study conducted by the Mayo Clinic found that digital health intervention for populations with early-stage CVD led to a 40 percent relative risk reduction and a 7.5 percent absolute risk reduction in CVD events, hospitalizations, and deaths.<sup>26</sup>

For the patient, digital health interventions can reduce the number of physician visits since devices can gather data via remote connectivity.<sup>27</sup> In addition, integration of wireless devices has reduced door-to-intervention times by an average of 66 minutes.<sup>28</sup> Furthermore, patient-education technologies are increasing consumer engagement and driving healthy behaviors.<sup>29</sup>

Interestingly, CVD patient populations with the highest prevalence of disease have the lowest digital adoption rates (Figure 4).<sup>30,31</sup>

From the provider perspective, digital solutions can serve as clinical-decision support tools for providers inputting patient data to generate treatment recommendations.<sup>32</sup> Moreover, there could be opportunities for significant in-hospital cost savings when providers leverage digital technologies. An observational study indicates an ROI of 10-15 times in the first 12 months by substituting a mobile cardiac telemetry for an event or Holter monitor.<sup>33</sup>

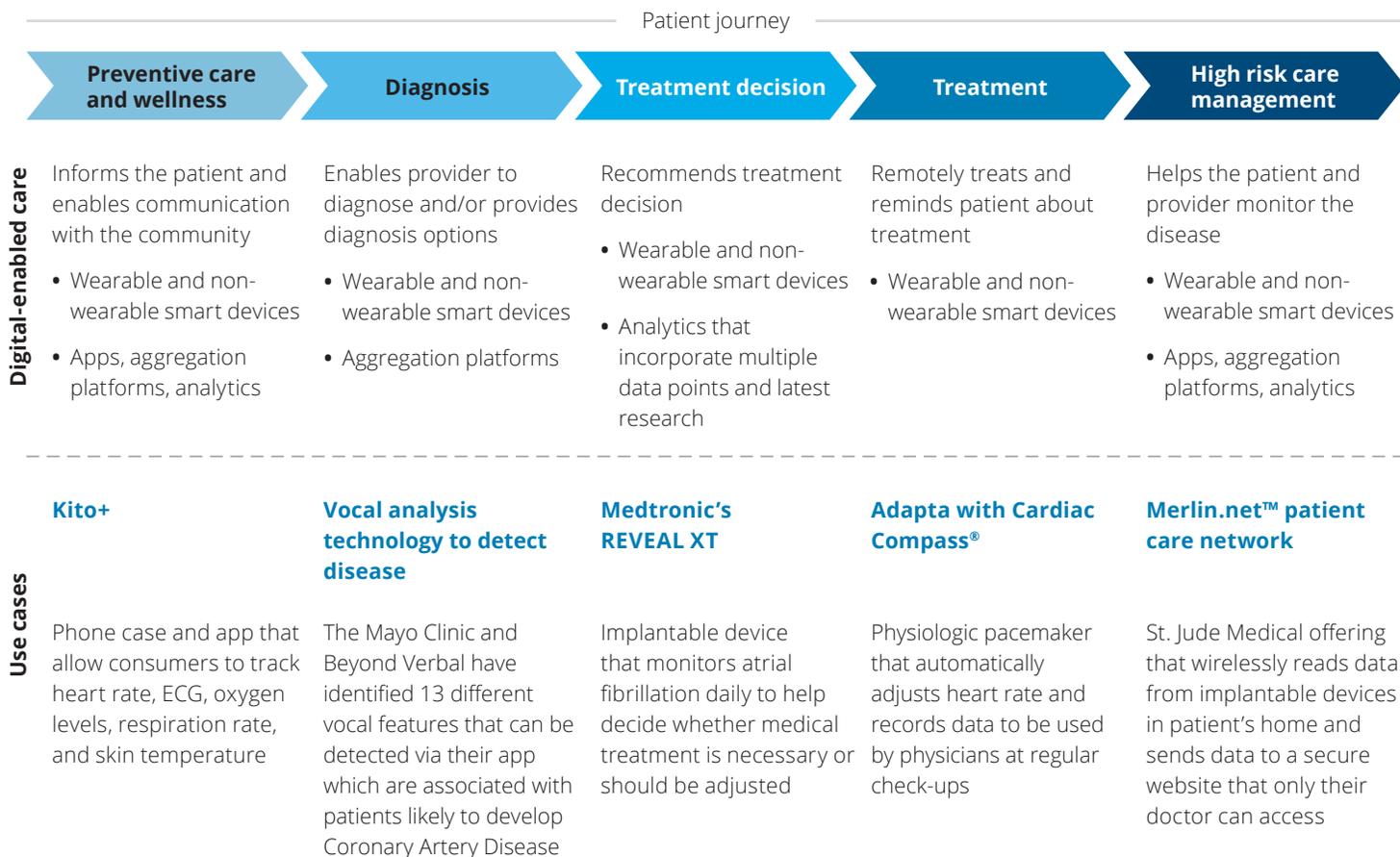
**Figure 4. Patients' digital health adoption**

CVD patient populations with the **highest prevalence** have the **lowest digital adoption rate**

 <b>CVD prevalence</b>		 <b>Used tech to measure fitness and health improvement (2015)</b>	
Age	Prevalence	Group	Used tech
20-39	10-12%	Millennials ('82-'97)	45%
40-59	36-41%	Gen X ('65-'81)	30%
60-79	68-69%	Boomers ('46-'64)	18%
80+	85-86%	Seniors (1900-'45)	13%

Cardiologists are benefiting from digital solutions, whose impact along the patient journey and on hospital operations can simplify, enhance, and accelerate how they provide care. Concurrently, increasingly active and aware consumers are seeing more availability of digital solutions to help them participate in their health care and treatment plans. These two dynamics are impacting how care is provided along the patient journey (Figure 5).<sup>34,35,36,37,38</sup>

**Figure 5. Digital solutions across the CVD patient journey**



## Glossary

**Analytics:** A mobile technology solution capable of performing complex data analysis through sophisticated algorithms and/or referencing empirical studies. Also often has aggregation-platform capabilities to pull in data from multiple sources to be analyzed.

**Aggregation platform:** A mobile technology solution that automatically aggregates data from multiple sources to make the range of data accessible in one central location.

**Non-wearable smart device:** mHealth-enabled device that does not require a user to wear it for a continuous period of time.

**Wearable smart device:** mHealth-enabled device that requires a user to wear it for a continuous period of time.

**App device/data connectivity enabled or required:** Mobile phone or tablet application that is capable of or requires a connection to another data source/device for automatic upload of data.

**App no device/data connectivity:** Mobile phone or tablet application that only allows manual data input and cannot connect automatically to other data sources/devices.



## Patient journey case study: Arrhythmia

Follow James, a healthy individual who has a family history of arrhythmia, across the patient journey to gain deeper insight into the use of digital solutions in CVD.



### Preventive care and wellness

James exercises, eats a balanced diet, and uses **smart devices** to track health metrics such as heart rate and blood pressure. At home one day, James feels fatigued and experiences shortness of breath and chest pain. Looking at his **smart device**, he sees he has an irregular heartbeat. He is rushed to the emergency room to be evaluated.



### Diagnosis

Clinicians assess James' vitals and ECG/EKG results and record his medical background and family history of arrhythmia. His abnormal ECG/EKG results indicate a need for additional testing, including: a) Holter Monitor, event or **loop recorder**; b) blood pressure (Tilt-Test); c) Heart stress test (Exercise ECG); d) electrophysiology studies (ES); and e) echocardiography (Echo). The emergency room provider diagnoses James with atrial fibrillation (A. Fib.).



### Treatment decision

The physician determines James' treatment path by confirming the diagnosis via consultation with the electrophysiologist, assessing the presence of comorbidities, and **consulting digital-based decision-support systems**.



### Treatment

James makes an appointment with his electrophysiologist (EP) to schedule a **pacemaker implantation** as a result of his diagnosed A. Fib. with a slowed ventricular response via a **loop recorder**. The pacemaker will help regulate and track his heart rhythm through frequent office checks and **remote monitoring**. An echocardiography revealed that James has moderate-to-severe mitral regurgitation, which puts him at an increased risk for congestive heart failure. James is released from the hospital.



### High-risk care management

Following his physician's advice, James exercises regularly, eats a balanced diet, and uses **smart devices** to monitor his cardiovascular health. Frequent pacemaker checks via **remote monitoring** can update his EP for arrhythmia burden, efficacy of antiarrhythmic therapy, and requirement/continuation of anticoagulation. James continues to educate himself about CVD, heart failure, and A. Fib. via his **smartphone**.

\* **bold** – Leverages digital solution

## Suggested steps for MedTech

Digital solutions allow physicians to simplify, enhance, or accelerate how they provide care, while empowering patients to take a more active role in their own care. MedTech companies should assess and pursue digital solutions based on their ability to predict a CVD event and reduce time to treatment, which are key drivers for physician adoption.



# 4

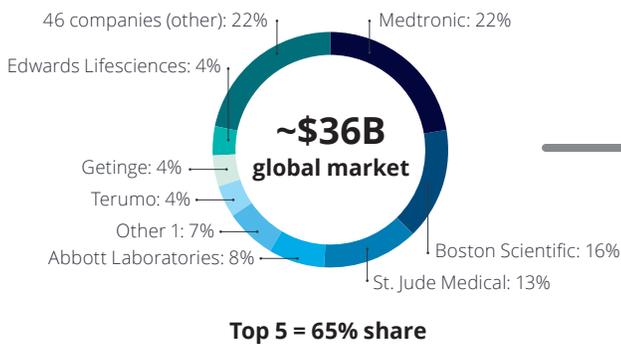
## Changing MedTech competitive landscape

As technologies to treat cardiovascular disease continued to advance from 2010 to 2015, the top five global CVD players' rankings shifted and their combined market share dropped five market share points, from 65 percent of a \$36 billion global market to 60 percent of a \$42 billion global market. And even though incumbents continue to own the market for traditional CVD products, the share of "others," which includes new entrants, has been slowly growing (Figure 6).<sup>39</sup>

**Figure 6. Cardiology key players market share trends**

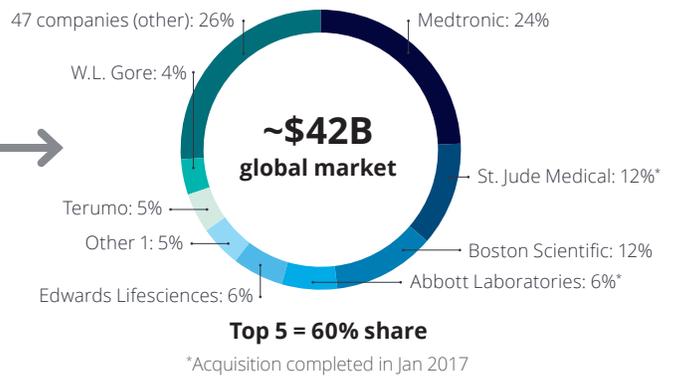
### Key players' market share (2010)

(Revenues as a percentage of global market)



### Key players' market share (2015)

(Revenues as a percentage of global market)



The cardiology market consists of cardiac assist devices, cardiac prosthetic devices, cardiac rhythm management (CRM), cardiovascular monitoring and diagnostic devices, cardiovascular surgical devices, electrophysiology, and interventional cardiology

With its \$54.2 billion market opportunity by 2020,<sup>40</sup> cardiology presents an attractive target for non-traditional MedTech players—if they can offer high-impact solutions supported by credible evidence. For example, in October 2015, the American Heart Association (AHA) and Verily (a Google Life Sciences company) engaged in a \$50 million research collaboration to support novel strategies for treating coronary heart disease. The goal of the five-year joint commitment, the largest one-time research investment in AHA's history, is to understand, prevent, and reverse coronary heart disease. This partnership between a nonprofit organization and a technology company, one that excludes a traditional MedTech company, has the potential to disrupt traditional clinical research models.<sup>41</sup>

In April 2015, IBM Watson Health and Apple established a collaboration to provide a secure, cloud-based platform and

analytics for HealthKit services by Apple Inc. This move could lead to better CVD treatments based on improved research and innovative solutions, increasing the relevance of nontraditional MedTech players in the CVD space. The open platform also allows access to the latest CVD thought leadership.<sup>42</sup>

Qualcomm Inc. and Northern Arizona Healthcare (NAH) began collaborating in 2011 to build advanced wireless care technologies for discharged CVD patients. The goal was to provide a smooth transition of patient biometric information to a physician and enable remote health monitoring of patients.<sup>43</sup> Nontraditional MedTech organizations, such as Fitbit and Whoop, are also providing heart monitoring solutions from a consumer device perspective.<sup>44,45</sup>

In addition to collaborations among nontraditional players, established MedTech companies are engaging in deals to consolidate portfolios and acquire new entrants. A number of MedTech companies are consolidating to blend complementary portfolios and gain scale (Figure 7).<sup>46,47,48,49</sup> One key example is Abbott's acquisition of St. Jude Medical, consolidating the second- and fourth-largest CVD players by market share in 2015.

**Figure 7. Examples of key cardiovascular deals: Consolidation**

Acquirer	Target	Value	Date
Abbott	St. Jude Medical	\$25B	Jan 2017
Medtronic	HeartWare	\$2.7B	Aug 2016
St Jude	Thoratec Corp	\$3.3B	Oct 2015
Cardinal Health	Cordis	\$1.9B	Oct 2015
Cyberonics	Sorin	\$2.7B	Feb 2015

In parallel, MedTech players are also acquiring new entrants that offer innovative technologies (Figure 8).<sup>50, 51, 52, 53, 54, 55, 56</sup>

**Figure 8. Examples of key cardiovascular deals: Acquisition of innovative technologies**

Acquirer	Target	Value	Date
Abbott	Tendyne Holdings & Cephea Valve Technologies	\$225M	2015
	Topera	\$250M	2014
Boston Scientific	Lazarus Effect	\$100M	2015
	Rhythmia Medical	\$90M	2012
Edwards Life Sciences	CardiaQ	\$400M	2015
	Twelve	\$458M	2015
Medtronic	Cardioinsight Tech	\$100M	2015
	Corventis	\$150M	2014
	Cardiacom	\$200M	2013

- Treatment of Atrial Fibrillation/ Atrial Flutter
- Mobile Cardiac Telemetry
- Transcatheter Mitral Valve Tech
- Remote patient monitoring and disease management

## Suggested steps for MedTech

The CVD MedTech market is becoming ever more competitive as established players increasingly compete with new entrants to provide innovative treatment solutions. MedTech organizations should assess how best to incorporate innovative offerings via a range of collaborations, investments, and/or acquisitions.



# 5

## Evolving provider and care delivery shifts

The profile of a typical cardiovascular provider is changing, the result of physicians increasingly switching from private practice to employment in provider networks, an aging workforce, and the impact of new care delivery standards on clinicians' traditional roles.

Cardiovascular physicians are leaving private practice and joining provider networks;<sup>57</sup> reportedly they are frustrated by the growing amount of time spent managing businesses versus providing care.<sup>58</sup> About 30 percent of private practice physicians have opted to merge with a hospital where they are incentivized to provide good care, driving higher-quality outcomes.<sup>59,60</sup>

In addition, the cardiovascular physician workforce is aging and facing declining productivity. Thirty percent of the workforce is over age 59. In addition, this group is 19 percent less productive when compared to cardiologists between the ages of 49 and 53.<sup>61</sup>

Finally, cardiovascular care increasingly is being provided by non-cardiologists. This trend includes shifting certain treatment activities, including prescription writing, from physicians to nurse practitioners (NPs) and physician assistants (PAs)—and the scope of allowed activities is growing.<sup>62</sup> It's anticipated that the supply of NPs and PAs will outpace demand, and the health system will need to absorb it, likely in specialties versus primary care.<sup>63</sup> This may contribute to the increased number of non-cardiologists who engage with the patient during their health care journey. In a change on the cardiologist side, some interventional cardiologists are performing more invasive procedures as a result of efficiency plays and volume consolidation.<sup>64</sup> This shift may potentially drive different sub-specialization needs, further impacting the profile of professionals caring for cardiovascular patients.<sup>65</sup>

### Suggested steps for MedTech

CV companies exploring their commercialization strategies should consider both the cardiologist and other providers engaged in patient care (e.g. NPs and PAs), whether for diagnosis, treatment, or high risk care management.

# Conclusion

As CVD MedTech companies grapple with new market realities, expectations, and success measures, leadership teams seeking a competitive advantage should begin by addressing the following questions:

- Given your existing solutions portfolio, should your organization adopt a mindset of incremental or transformational change? Perhaps your organization is already on a strong path to providing solutions in the context of broader trends, including VBC and digital solutions, and incremental change is needed to extend this strategy to your cardiovascular products. Alternatively, you may find that a transformational program may be necessary to provide the type of internal disruption necessary to succeed in this new reality.
- Where are the new business opportunities, and what role do you want to play in transforming care delivery models in cardiovascular? What will be your basis of competition in this new reality? For some companies, developing innovative digital services and solutions around traditional products may provide increased consumer and physician engagement and broader adoption. For others, identifying how they can holistically advance care within a cardiovascular space may provide a more advantageous path.
- To what extent do you need to rethink your go-to-market model and customer engagement mechanisms as the cardiovascular market shifts? Your current strategy likely includes the cardiologist as the key decision maker, but targeting a wider span of care providers, including NPs and PAs, may require transforming your business model.
- How will your product development approach be impacted by this new reality? Are there alternative models or external collaborations to consider? You may already be a leader in providing innovative technologies to the cardiovascular market and may be considering external collaborations to develop wraparound services and solutions. Alternatively, you may consider acquiring or partnering with companies that are creating cutting-edge technologies to fast-track your role in transforming care delivery.
- What is the end-to-end “readiness” view of your organization so you don’t just survive, but thrive, in this new reality? What capabilities should you strengthen and how should you invest? There may be existing strengths that you can leverage in other parts of your organization. You should holistically assess your organizational capabilities to determine what you should improve on and whether to build versus acquire.
- How should you align and adapt your corporate culture to better prepare for a CVD future that may look very different than today’s? You should create a burning platform that employees can rally behind and consider appropriate levels of change management so that your culture enables progress, instead of impeding it.

Developing and implementing strategies to address each of these focus areas can help MedTech organizations get to the heart of changes taking place in the CVD ecosystem; engage with patients, providers, payers, emerging competitors, and other stakeholders; and position themselves for competitive advantage.

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# Endnotes

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