2021 MEDICAL DEVICE TRENDS

2020 has been a highly impactful year for the medical device community as companies face new challenges from the coronavirus pandemic. With a reduction in elective surgeries, pushes to meet demand for ventilator manufacturing on significantly shorter timelines, and more rapid issuance of EUAs becoming more commonplace, in 2021 medical device companies will need to stay on top of trends moving toward remote medicine and wearables for monitoring purposes, perhaps considering M&A to do so.

TREND #1:

Remote medicine is gaining momentum

In the past, US physicians have observed barriers to telehealth, with major concerns tied to a history of **uncertainty around reimbursement and insurance coverage**. However, the 2020 coronavirus pandemic has made remote medicine more important, more relevant, and more accessible than ever, as reimbursement has become more widely accepted. Telemedicine has also become more accessible in part because of the increase in wearable med devices, allowing doctors to measure patient health parameters such as heart rate and respiration remotely. For example, **Philips was granted 510(k) clearance** for a biosensor to help clinicians remotely observe a patient's heart and respiratory condition, highlighting how remote monitoring is likely to become more common in 2021.

CLARKSTON CONSULTING

While remote monitoring devices are helping to push telemedicine forward, using devices remotely may change the way that practices decide to make med devices purchases. For example, patients may currently use med devices, such as a holster heart monitor, away from an office temporarily but return it soon after receiving a diagnosis. Making medical devices to be used for longer term remote monitoring will likely rely on their ability to consistently access the internet and connect with the doctor's office. This type of remote health application also increases the need for strong cybersecurity measures, especially since medical devices may now come in the form of software to improve connection and compatibility with wearables. **Medtronic even recently developed a mobile app** to help connect pacemakers to patients' smartphones to help them better use health data for remote monitoring.

An increase in the popularity of telehealth could affect geriatric medicine in a particularly unique way. In the past, these patients may not have considered remote medicine to be a viable option, but as accessibility increased during the pandemic, they may be more likely to move forward with more of a 50/50 split between telehealth and in-person appointments. However, if half of check-in appointments become remote, this may affect the quantity of medical devices that need to be purchased for a practice, such as weight scales for example, in balance with devices that can be used for telemedicine. This highlights considerations for medical device companies as we move into a more remote-focused 2021.

The percentage of visits by telehealth among health centers in the U.S. dropped from a peak of 53% in late April to only 31% in August 2020.

SOURCE

TREND #2:

EUAs are becoming more commonplace

Because of the coronavirus pandemic, in 2021, FDA emergency use authorizations (EUAs) are likely to continue becoming more common, especially in comparison to most companies' practice of initially making requests for 510(k) clearance. In the past year, these EUAs have been implemented for factories and ventilators, with Resmed achieving 24 and Philips achieving **12 respiratory device modification approvals** eligible for EUAs in late March 2020. EUAs have also allowed established medical device manufacturers to create rapid tests for COVID-19 preventions and invitro diagnostics. The EUAs have helped medical device companies increase availability and speed for diagnostics, while still providing a level of quality and safety. With **outdated regulation policies** dating back decades, the ability of EUAs to reduce hurdles for medical device manufacturers hoping to move more flexibly may become more of a foundational model coming out of the pandemic.

TREND #3:

The lasting effects of COVID-19 on medical device companies reliant on elective surgeries

The 2020 pandemic and subsequent national shutdown directly influenced the medical device industry as demand for certain products skyrocketed while others came to a halt, as was the case for devices used in elective surgeries. For many of these companies, business had seemed to be stable and steady with consistent demand from patients for a long time, especially for surgeries like knee and hip replacements. Because of how this element factored into 5- to 10- year plans, many medical device companies had to make rapid adjustments for coronavirus shutdowns, whether through employee furloughs tied to high sitting stock levels, whether they started to produce more urgently relevant devices such as face shields or ventilators, or whether plant updates or maintenance could be conducted in the place of rapid production.

Due to COVID-19, in May 2020, there were 17 EUAs for ventilators, with the most (6) going to Resmed.

SOURCE

While important, these adjustments have a short-term focus, meaning that long-term strategic reassessment may not be in the spotlight when it could or should be. As a contrasting example, in other

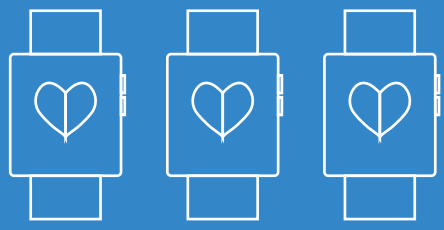
industries such as CPG, many companies were reconsidering their balance sheets and assets prior to the pandemic as they struggled to utilize their full capacity, but now production capacity is actually proving to be a bottleneck as they attempt to keep up with high demand. In comparison, medical device makers that were negatively impacted, however, may instead need to consider their ability to be flexible or agile from a manufacturing perspective. While **elective surgeries are starting to return,** the flow of cases **may not become steady right away,** meaning that medical device manufacturers may need to consider rethinking operations to find ways to cut costs for now to better handle uncertainty in 2021, perhaps looking at strategic planning through the lens of enterprise destination mapping to ensure that goals are clear and able to be reached moving forward.

Early in the pandemic, surgery centers were only completing 6-10% of the standard volume for procedures.

SOURCE

It is estimated that approximately 2 out of 3 clinical trials will incorporate wearable sensors by 2025.

SOURCE



TREND #4:

Making more space for wearables and their capabilities

In 2020, wearables made a significant impact on the way the healthcare industry handled treatment for the coronavirus pandemic. For one, they better enabled remote monitoring, which became paramount for clinical trials and for alleviating concerns of patients about in-person doctors' visits. Additionally, wearables were actually able to help in coronavirus symptom monitoring and early detection. In a study, Fitbit wearables detected **50% of coronavirus cases a day before symptoms were reported.** Tied with an overall increase in people's willingness to wear fitness trackers, wearables can continue to help with prevention, detection, and management with health monitoring for heart rate, ECG, glucose levels, and **in some cases, environmental factors like allergens, which may impact a patient's health.** In 2021, it may become more common for wearables to also improve their ability to treat certain symptoms through temperature changes or vibrations.

Tracking and fully utilizing all health data generated by wearables can be a large responsibility for health care providers to manage, but

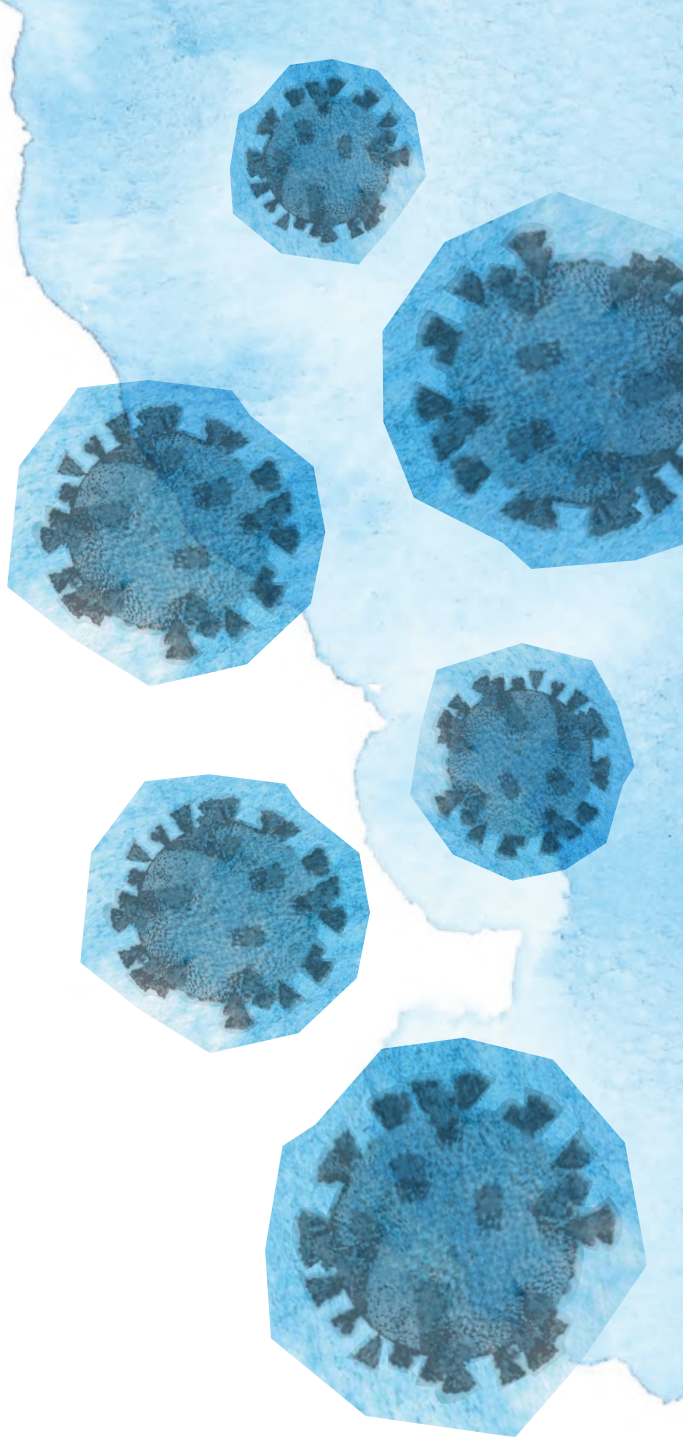
this is an advantage in wearable use in clinical trials. In this case, wearables can help reduce the length and frequency that patients must participate in clinic visits. **Whoop wearables** are currently being used in a Phase III trial for a coronavirus vaccine, helping to keep track of certain health data points and overall wellbeing, which has been the first application of a wearable technology in this kind of clinical trial. Additionally, data collected by wearables can help aging populations better prevent and manage chronic conditions, especially with an increase in advanced elements available through wearables. For example, the Apple Watch Series 6 provides blood oxygen monitoring, though the technology **still has room to improve,** especially since the technology has not been approved by the FDA and is not a medical device intended for use in diagnosing disease. Women's health and mental health also represent areas of further opportunity for wearables in 2021.

TREND #5:

M&A in 2021 may continue to be impacted by the coronavirus pandemic

In June 2020, the transaction value for healthcare and life sciences M&A in the U.S. reached a **significant low,** at $21.5B compared to the next most recent low of $101.6B in 2012. However, while med device M&A deals were slow moving and primarily made in diagnostics in early 2020, late summer into early fall produced a major rise in deals moving into the digital health space.

Siemens Healthineers acquired Varian for cancer treatment technology-- a takeover that was pushed forward by challenges faced from COVID-19, Teladoc acquired Livongo to better prepare for a rise in telemedicine, and Illumina bought Grail for liquid biopsy resources. One key aspect to note about the Varian takeover was the fact that another major bidder was also involved, which indicates a continuing trend as interest in acquisitions remains strong. In other instances, hospitals and labs that have been affected by the coronavirus pandemic may also possibly see more M&A activity, especially since larger labs like **Quest and LabCorp** seem to be better able to handle the changes brought by the pandemic. This trend may also extend into other medical device companies with poor performance right now, setting the stage for them to be part of a takeover by larger companies currently performing better with the ability to move forward with M&A throughout early 2021.



In September 2020, U.S. M&A deals in the medical device segment were valued at $9.35B

SOURCE

TREND #6:

MDUFA fee schedule rate changes and the future of lobbying

For 2021, US FDA medical device user fees will be higher by 7% compared t 2020 user fees. As of October 1, 2020, this new fee schedule has been in effect for both standard fees and the small business determination program. However, the coronavirus pandemic caused organizations such as hospitals and dental offices to suffer greatly from a significant drop in demand for elective surgeries, which subsequently hurt medical device companies in thi segment.

DA medical device user fees were increased by 7% increase in the 2021 fiscal year.

SOURCE

Moving into 2021, it could be much more difficult for these companies to recover to begin with, made even more difficult by the fact that they must also pay higher user fees. Therefore, the downfalls of 2020 could potentially impact future lobbying efforts for med device companies. Fee increases continue to be expected in coming years, so especially with new uncertainty highlighted in the pandemic left unresolved, lobbying efforts may shift. These efforts may adjust in order to seek options to have more clear and effective differentiation between bigger and more established companies from smaller startups, perhaps taking note of the difference in the ways these companies were impacted in 2020 by both the pandemic and the most recent user fee increase. No matter what, the impact of the pandemic will provide an interesting layer to the talking points and actions that lobbyists perform for restructuring or delaying future fee increases.

Looking Ahead

Moving into 2021, lasting effects from the coronavirus pandemic will continue to make a difference in the way medical device companies make strategic movements. With a rise in tech capabilities and changes in the way the industry has operated in the past, it will be important to keep a focus on the interests of the patient and opportunities for growth after a period of uncertainty.

ABOUT CLARKSTON CONSULTING

Businesses across life sciences industries partner with Clarkston Consulting to enhance strategic decision making, improve operational efficiencies, implement new technologies, and promote business growth and market diversification. Leveraging deep functional and industry expertise, our people discover, design, and deliver solutions that fit your business, your goals, and your future.

For more information about how we can help your company with the challenges and opportunities in medical device, please contact us.

CLARKSTON CONSULTING