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Medtech's Move To Business Process Orchestration

Today's Patient-Centric World Driving Continued Transformation

Medtech companies have always been patient-centric organizations. Yet today, with the point of care moving from hospitals to homes and physicians evolving from authorities to guides, what it means to make patients the focal point of operations is changing. These changes interweaved with market access, value-based pricing and reimbursement, digital health, new regulations and the pursuit of innovation are forcing transformation for companies looking for global excellence. Addressing these changes, companies need to orchestrate across their business processes to thrive.

The role of patient-centricity is further evident with the rise of digital health. Breaking digital health into its component parts, which include connected devices, software as a device, patient data and real world evidence, and personalized devices shows the central role patients play and the importance of human data science in a digital health world.

USING DIGITAL HEALTH TO BENEFIT PATIENTS

Connected devices that can be modulated to facilitate personalized care and remote monitoring are a direct manifestation of patient-centricity. Treatment can be monitored and tailored to the specific needs of the patient and the continued growth of 3D-printed devices exemplifies ways in which companies are leveraging innovation to meet both speed-to-delivery and patient-specific care. Patient-centricity is also evident in connected devices that can constantly gather data on patients. When combined with data captured by software as a device products, such as medical apps, which can include geo-centric and other physical and personal data, the output of connected devices in our IoT (Internet of Things) world we operate in today yields unprecedented insights into the day-to-day health of individual patients and can be used to identify clinical trial populations and even support virtual trials.

Importantly, patients are increasingly in charge of the data behind these insights. Ownership of data is shifting from institutions to consumers, putting patients in control of how their information is aggregated for population-level analyses that improve care. Analysis of digital health data is part of a broader effort involving real world evidence (RWE). That effort is based on four main sources of longitudinal data: medical records, prescription data, hospital encounters, and claims from payers, hospitals and drug plans. While RWE is typically thought of in the postmarket context, the value of its insights extends across the value chain. RWE informs everything from device concepts and trial designs to health care professional

training and the generation of evidence to support premium pricing in a value-based health care environment. Thus, it is a concept to consumer and back again environment that requires business process orchestration to fully leverage the benefits.

Business process orchestration permits such company-wide use of RWE by breaking down silos while overlaying quality, regulatory, safety and other functions from clinical to commercial that span the entire product life cycle. That means people working at each step in the value chain from concept to market have access to information both upstream and downstream of them.

Each component of digital health is powerful in isolation. However, their full potential only becomes apparent and fully realized when they are combined. Together, the components are facilitating virtual trials by enabling sponsors to remotely identify participants and collect data from them, streamlining the process of generating evidence to support claims about a device.

INNOVATION IN THE BIG DATA DIGITAL HEALTH ERA

The proliferation of data is happening in unison with a related expansion in advanced analytic capabilities. Faced with the need to analyze data from sources such as connected devices and other external data sources, medtech companies are leveraging the power of cloud computing along with machine learning (ML) and artificial intelligence (AI). These advanced technologies are enabling companies to get insights from big data and perform predictive analytics and better risk management.

Medtech companies have always innovated faster than their pharmaceutical counterparts. The rise of data and advanced technologies is further accelerating that pace by equipping companies to quickly make data-driven and risk-based assessments of what patients need and develop products that address them. Patient-centric digital transformation is mirrored by changes in physical products, which can now be personalized to individuals.

New products are only one part of the innovation story, though. To meet the needs of patients around the globe, medtech companies also need to understand the regulatory pathways and requirements to get existing devices into new markets. Orchestration across regulatory intelligence data (RID) and regulatory information management (RIM) along with enterprise quality management (eQMS) solutions are the backbone of getting products more quickly and efficiently into new markets. In some cases, medtech companies can enter additional markets with minimal new trial efforts or trials and approvals from other markets, thereby quickly bringing benefits to millions of patients. Where trials or data are required for market approval, business process orchestration and real-world evidence will facilitate accomplishing this more effectively without adding significant costs.

Entering new markets extends the life cycle and overall profitability of products and maximizes the benefits they provide to patients. However, the effectiveness of innovation and compliance strategies rests on a company's ability to operate from an overall business process orchestration perspective globally across traditional functional and geographic silos. Integrated solutions implemented in a business process orchestration fashion in concert with one's clinical, compliance and commercial operation systems and processes can quickly identify the best opportunities, improve decision-making and facilitate operational excellence.

HOW PATIENTS ARE RESHAPING REGULATION

Changing regulations are also driving companies to relook at how they orchestrate compliance across their operation. Patient-centricity underlies changing regulations and product innovation and improved safety is a by-product. The focus on further enhancing patient safety, manifested in new and constantly evolving regulations, will require medtech companies to capture and report additional data on their products. These regulatory changes may create challenges related to product reclassification and approvals through notified bodies in the near term, but medtech companies that adapt effectively to the new regulatory environment will be best positioned to reap the benefits long term.

Those benefits stem from the fact that companies as well as regulators will have more and better data on their products. Regulators glean insights from the data that enable them to take a more informed, risk-based approach to oversight, reducing auditing of some companies on the grounds that the data provide confidence in their compliance. That too will benefit patients by increasing scrutiny of high-risk products and companies. Medtech companies, in turn, can use data captured in orchestrating their business processes from research and development and clinical trials through commercial operations and service providers for not only compliance but additional evidence and analytic capabilities to further innovation and operational excellence.

WHY BUSINESS PROCESS ORCHESTRATION?

Companies will, and are, moving past a focus on simply integrating disparate systems and siloed groups to one that fosters and operates in a true cross-functional and extended enterprise collaborative fashion. Operating across business processes, including the systems and technology to support the needed business process orchestration illustrates how leading companies will further adapt to the transformation and leverage being driven by digital health, regulatory change, and patient-centricity.

To achieve this entails taking a business process view of the full medtech product life cycle, from concept to market, and bringing together the technology, products, services, consulting, data and technology-enabled managed services necessary to combine each link in the value chain. In practice, these changes will require medtech companies to use the collective resources and industry expertise they possess and that of their trusted partners.

Business process orchestration is a new way of working for many medtech companies but it is a necessary change. Companies that make this transformation with be best positioned to emerge from these times of change as industry leaders. As patient-centricity, digital health and regulatory changes are behind many of the forces reshaping the medtech industry, companies that put the patient and data at the center of their innovation will be the long-term winners.

Successful companies will leverage deep and unmatched domain expertise, transformative technology, unparalleled data and advanced analytics while adopting business process orchestration, equipping them to improve their operations while keeping patients at the center of every decision.