Medtech's Path Towards Patient-Centric, Paperless Trials

For Medtech companies running clinical trials, 2020 may go down in history as "the year of evaluating everything." More than 100 companies reported trial disruptions[1] because of COVID-19, and nearly 1,800 studies were impacted.[2] However, clinical innovation and change are happening at a rapid pace as leaders rethink how studies are run.

Clinical trials are critical in demonstrating a medical device's safety and effectiveness, but traditional studies lack agility and flexibility. The slightest protocol change can lead to manual data entry across multiple systems and platforms, slowing down trials. These delays increase development costs and could ultimately impact the price of the end product. Additionally, disparate systems create process gaps, inefficiencies, and introduce the risk of non-compliance.

With a rapidly changing global market and an evolving regulatory environment, the industry is looking for more connected, digital ways of working throughout the study lifecycle. Medtech companies are leading the way and adopting new virtual, remote, and digital solutions. The shift will deliver a better overall patient experience in studies, improve collaboration, and accelerate how products are brought to market.

[1] BioPharma Dive, A Guide to Clinical Trials Disrupted by the Coronavirus Pandemic, May 15, 2020
[2] The Grey Literature, Clinical trials stopped by COVID-19, 2020

Enabling Patient-Centric Trials to Improve Data Quality

Data requirements across studies, from trial conduct to study monitoring, are growing. Medtech companies are improving outcomes by adopting solutions, such as virtual visits or remote data capture, that enable patient-centric approaches. These new methods of engaging patients can deliver quality trial data, reduce the patient burden, and accelerate research. Increasingly, trials are no longer conducted just for regulatory approval, but increasingly throughout the product lifecycle to show additional value to payers, providers, and patients.

Solutions that support virtual visits allow patients to attend check-up appointments from the comfort of their own home. Wearables like smartwatches and fitness trackers make patient data collection easier for participants and care providers. Giving patients the flexibility to participate and engage anywhere, anytime, can simplify study execution.

One example is eConsent, an entirely new approach to managing patient permissions. Instead of paper-based processes that are resource-intense and manual, eConsent streamlines and simplifies the consent process, from authoring to patient signature. Patients can even review documents and protocols and provide consent from their mobile phones. The flexibility to access trial information also makes it easy for patients to reference important documentation during and after the consent process.

Medtech companies have been leading digital and remote care to support patients and are now embracing patient-centric trials. It is also a focus for industry organizations, such as at the public-private partnership at MDIC, who are advancing patient-centered policy, product development, and regulatory decision making. With patient-centric approaches, studies for devices and diagnostics can produce more reliable, fully compliant data.

Digitizing Processes to Run a Paperless Trial

Although 54% of device and diagnostics industry professionals anticipate a full recovery in clinical study activity before the end of the year,[3] many are tackling the ever-increasing costs of running clinical research. To streamline clinical trials, companies are shifting from paper-based processes and digitizing.

The FDA's release of ICH-E6(R2) supported the industry's move to digital with specific guidance that provides digital alternatives to help accelerate research. One alternative is ePro, for example, which allows patients to report on study outcomes such as improvements in health or adverse reactions through an online form.

Companies are also adopting eSource to collect and record patient data digitally in a compliant and audit-ready way. Research sites no longer have to capture data on paper and manually enter it into an EDC. Without tedious paper-based processes, sites can speed trials by spending less time on administrative tasks and more time with patients.

By improving trial processes with solutions such as ePro and eSource, Medtech companies can achieve better data quality and improve trial efficiency.

[3] Veeva Systems, Modernizing Clinical Trials: Keeping Pace with Medical Device and Diagnostics Innovation, 2020

Improving Collaboration to Drive Innovation

A connected clinical landscape across sponsors, CROs, and sites make seamless information sharing a reality. By aligning stakeholders on processes and providing real-time access to information, Medtech companies can improve efficiencies and speed studies.

For example, sponsors can gather feedback from sites on study feasibility and spend less time coordinating surveys. They can also distribute safety letters faster to notify global sites and regulators of an adverse event and get real-time patient updates from enrollment to treatment.

For sites, streamlined collaboration frees up time for delivering care to patients. This is especially important for Medtech trials where surgical centers and other institutions without dedicated clinical trial staff are frequently utilized due to their specific therapeutic expertise. These sites repeatedly partner with sponsors for multiple products, leading to duplicated efforts during site initiation. Medtech companies can significantly simplify the process through connected data networks.

Bringing together studies across stakeholders improves essential document exchange and collaboration, making trials more efficient, effective, and secure. The most significant benefit is the shift of focus from administrative and mundane tasks to patients and the products that can help improve their conditions.

Centralizing Clinical Data and Processes for Faster Execution

Medtech companies are looking for ways to accelerate the product development lifecycle and bring products to market faster. Leveraging one platform for data, content, and process management allows organizations to build and run more trials.

Cloud-based solutions that streamline electronic data collection (EDC), coding, study start-up, TMF management, trial operations management, and site document exchange improve how teams work together by providing widespread access to data across study stakeholders. These products ideally would be integrated to deliver a seamless clinical experience across operations and data management.

EU IVDR and MDR are two drivers for companies to centralize clinical data and processes to improve how outcomes are shared with governing bodies. Leveraging a single platform to manage clinical trial data and processes ensures that as new changes to regulations are released, the latest global regulatory requirements are applied within your system automatically. The releases provide visibility and control over critical compliance processes for audits and allow organizations to remain inspection-ready.

More efficient approaches to collecting, analyzing, and reporting clinical data are crucial to the economic feasibility of products since EU IVDR and MDR both have the requirement of continued clinical evaluation, both pre- and post-market. Unfortunately, many companies are undergoing portfolio rationalization due to these changes. Some of which may directly impact patient access to appropriate treatment options.

Centralizing data can improve efficiency and visibility by driving end-to-end processes from development through commercialization and post-market evaluation. With this infrastructure in place, medical device and diagnostics companies can accelerate product development and maintain compliance.

Advancing Toward Patient-Centric, Paperless Trials

The "year of evaluating everything" represents a significant opportunity to modernize clinical research and drive positive change amidst disruption across every aspect of healthcare delivery to patients. The industry is embracing solutions that digitize processes and improve collaboration to enable patient-centric, paperless trials.

By replacing manual and paper-based processes with digital and virtual methods, Medtech companies can drive higher quality study results and patient satisfaction. With the tools, technology, people, and processes in place, industry leaders can have peace of mind that they can be fully compliant and audit-ready while undergoing positive, transformative change.

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