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Bring Your Medical Device Trials To Market *Faster*

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There's no denying that the medical device industry has seen a tidal wave of competition in recent years. **Forbes forecasted that this $518 billion industry will be a disruptor in the healthcare technology space through 2023, if not longer.** [1,2]

Although the market used to be dominated by large medical device companies like Abbott Labs or Johnson & Johnson, we're now seeing medium and small-sized players from the startup community keeping pace. Even companies in the lifestyle market like — Fitbit and Apple — are seeing an opportunity to seize a large portion of the market by offering unique features and functionality on their wearable devices.

Thanks to a mixture of digital transformation in the device industry and increasing use of wearables and devices in our day-to-day lives, there is not only growing demand for new devices, but also growing complexity.

As competition and complexity grow in the industry, medical device companies face the challenge—eat or be eaten. Organizations need tangible ways to increase their efficiencies and reduce trial costs so they can beat out the competition and reach market launch first.

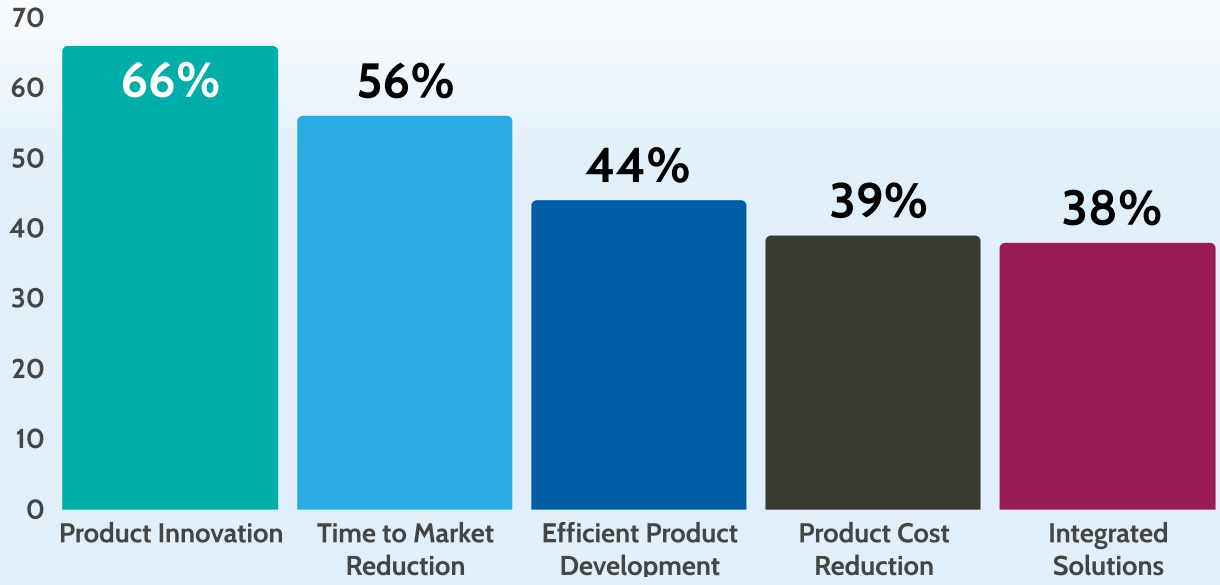
This paper will explore proven pathways to bring your medical devices to market faster, without compromising on the quality of your clinical data or outcomes.

Striking a Balance Between Speed and Innovation

Medical devices have grown to dominate the clinical trials industry, and it's easy to see why. Medical devices play a pivotal role in the health and lives of millions of people globally. From common medical equipment, such as stethoscopes and tongue depressors, to complex implantables, surgical supplies, life-support equipment, and more. Devices are paving the way for novel treatments and the prevention of critical health conditions.

Over a decade ago, medical device manufacturing was focused on improving design and ensuring device simplicity. Today, thanks to the aid of emerging technologies, **the industry is dominated by two things—speed and innovation.**[3]

Top five competitive drivers for the medical device industry in the next five years[3]



But meeting patient demands through innovation, while getting the product to market faster than the competition, proves very challenging for many device companies.

Organizations reported targeting a 25% average reduction in development time for medical devices in the next five years in order to stay competitive.[3] For the average medical device trial, that means reducing development time by anywhere from three to 15 months.

To achieve faster time-to-market, device companies need to make difficult choices. When innovation is achieved at a rapid pace, like what is happening in the medical device space, it can outpace regulators' ability to provide up-to-date clinical guidance. Similarly, larger device manufacturers that are working closely with clinicians and advocacy groups to identify unmet patient needs and indication for use, are struggling to convert feedback quickly and tangibly into a deployable device.[4]

To keep pace with the speed and innovation necessary to stay competitive, many device companies are exploring every opportunity to increase clinical efficiencies and reduce costs.[4]

Proven Methods to Get Your Medical Devices to Market Faster

1. Reduce or Remove Paper Processes

Medical devices have come so far in recent years including the introduction of remote biometric monitoring solutions for chronic conditions, portable air purifying respirators for frontline workers, and even AI-equipped sensors to predict fall risks for the elderly.[5]

Yet, the medical device industry continues to rely heavily on paper forms.[6] In fact, a 2020 survey on the State of Medical Device Product Development and Quality Management found that **over 50% of medical device companies still use paper-based systems**.[7]

Paper processes may seem easier, more familiar, and more cost-effective upfront. But it's important to understand how paper can end up costing your trials in speed and innovation in the long-run.

Paper-based systems are naturally cumbersome.[8] Paper workflows, due to their inherently ad hoc nature, are limited and not built to withstand the complexities involved in overseeing the operations of a medical device.

Human-error plays a role, making it easy to misplace documents or lose track of the most recent version of a form. Worse, it is hard to maintain adequate security measures with paper forms. Trials end up relying on the security of their emails or transferring confidential patient health information via non-compliant routes.

If speed is a top priority, device researchers can't afford to fall victim to human-errors, manual processes, and unsecure systems. In order to move trials along quickly and safely, device companies need to reduce as many paper processes as possible. Flexible tools exist that support a mixture of paper and electronic workflows, filtering all data into a singular database for easy visibility and data-driven decisions.

As the industry moves toward a more digitized future, device companies cite four key benefits of adopting digital technology: [9]

- Cost reduction by 50% per participant compared with current onsite clinical trial methods.[9]
- Increased recruitment rate and diversification by making trial participation more convenient.
- Increased data collection from participants, since longer time spans can be monitored.
- Increased data quality based on participants' natural environment instead of data collected by survey at the trial site.

As more companies realize the benefits, they are aligning their trial strategies and designing new devices and wearables to enhance the collection of data and improve direct communication with patients, making it possible to adjust their studies on a timely basis.

2. Find Technology That is Right-Sized for Medical Devices

Medical device trials differ from their pharmaceutical and life science counterparts. Therefore, if a company is prioritizing speed-to-market for their intended device, having technology vendors experienced in providing efficient and cost-effective solutions for device companies is imperative.

Technology vendors that work regularly with medical device companies understand the pressure to get trials up and running faster. They can ensure that the technology is right-sized to fit the specific needs, speed, and specifications of your device trials.

What does right-sized technology look like?

- The technology should be easy to use and learn so device researchers can quickly and autonomously get their product to go-live.
- The technology should have flexible interfaces that remove unnecessary bells and whistles and create standardardized workflows for efficient trial management.
- When technology isn't right-sized for devices, companies can end up paying for features or hidden costs they don't need. Right-sized technology should have transparent pricing with predictable costs based on your usage.
- Right-sized technology shouldn't require specialized staff.
- Technology that is right-sized for devices will come with pre-built workflows such as randomization, blinding, and patient-reported outcomes that are more common in device research.

- Right-sized technology will be built for relevant medical device outcomes.[10] Defining these outcomes can often be complex due to the variation in devices and unique biomarkers or imaging techniques.

3. Reuse Technology to Help Reduce Cost and Time-to-Market

As unique as medical device trials are from pharmaceutical studies, there are patterns that emerge from device research. Although some devices are truly unique and new, it's common for device development to be an iterative improvement on existing devices. When this is the case, clinical data may be required to evaluate the benefits and risks of the new devices, but not as necessarily extensive as the original device.

For this reason, it can be highly beneficial for medical device companies to reuse right-sized technology in their trials. When technology is reused from trial-to-trial, it impacts the speed of device research by:

- Standardizing repetitive and redundant workflows.
- Allowing teams to build upon existing workflows, forms, queries, and functionality.
- Encouraging teams to select components that reduce safety risks and test loops.
- Reducing the regulatory and validation burden.

4. Integrate Your Clinical Trial Technology

Having the right-sized technology can significantly improve the speed and innovation of your device trials. But what happens when your technology doesn't talk to each other?

A single device study for a pacemaker may require multiple solutions:

- An electronic data capture (EDC) platform for trial data collection and management at the site-level.
- A clinical trial management solution (CTMS) for complete study oversight.
- A randomization and trial supply management (RTSM) solution to manage clinical operations and randomized trial logistics.
- An electronic patient-reported outcomes (ePRO) for participants to consent and record their diary entries on a web-based portal.
- An eConsent module for participants to consent in-clinic or remotely to the study.

If the trial is operating across four disparate systems, it can cause greater delays, frustration, and complexity for the trial. Device companies benefit from integrating their clinical trial technology across one unified platform.

When your EDC serves as your single source of truth for trial data, for example, it can offer real-time insights to study teams and sites. With instant access to study data, the trial operators of the pacemaker study can see when patients aren't filling out their web-based diary. They can trigger alerts that remind the participants when it's time to submit an entry or identify if there is a lapse in adherence to what's expected of the patient.

Similarly, insights can be shared quickly between teams which can help device companies make decisions that protect their trial timelines.

5. Be Prepared for Mid-Study Changes

Even the best planned-for and executed studies face the dreaded wrath of mid-study changes. They are a facet of clinical research and devices are not exempt.

Device design or protocols may be changed during a trial due to early clinical events or direct feedback from clinicians or patients. Validation of these changes may require additional clinical data beyond the initial plan, as well.

When this happens, a study by the Tufts Center for the Study of Drug Development (CSDD) found that it can cause **delays of up to 40 days to resume a trial after the mid-study change**.[11] For fast-paced device studies, that will greatly impact their time-to-market.

In order to keep pace and stay competitive, it's critical that device companies use technology that reduces downtime and overall impact of mid-study changes. Flexible interfaces that allow teams to review and deploy changes safely from a test environment to the live study can help keep study timelines on track.[11] In fact, survey respondents who identified as "more satisfied" with their technology's ability to manage mid-study changes reported a five-day advantage to resuming their trials. But this is especially helpful, once again, when deployed across a unified system so disruptions and downtime are minimized across the technology stack.

In addition to having the right technology in place, teams will want to ideally plan for mid-study changes. The same Tufts study found that **when mid-study changes were planned for, the changes took 1.5 fewer days to go-live again**, compared to unplanned changes.[11]

6. Use Real World Evidence in Your R&D

Real world evidence (RWE) is a data collection method that is being increasingly accepted by regulators and adopted by device companies.[12] Rather than waiting for the conclusion of a trial to collect and analyze real-life data, valid trial data can be obtained outside of the content of randomized control trials.

The FDA defines real-world evidence as: "Healthcare information derived from multiple sources outside of typical clinical research settings, including electronic medical records (EMRs), claims and blinding data, product and disease registries, and data gathered by personal devices and health applications." [13]

This data essentially compliments the knowledge gained through traditional clinical trial data. This is because trial data can be limited, making it hard to generalize findings to larger, more inclusive patient populations.

RWE can come from clinical data, administrative data, patient-reported data, and emerging data sources such as social media or other disruptive technologies.[13] RWE is more traditionally leveraged by pharma companies that are managing larger quantities of data. It can play a greater role in assessing device efficacy, especially in situations where randomized control trials do not or cannot provide the data needed.

Incorporating RWE as an integral component of the data package on a product across the lifecycle increases the knowledge of all stakeholders regarding potential benefits and side effects of the intended product. With more robust data, improved methodology, and greater clarity about regulatory frameworks, RWE analytics in the short term could support:

- More targeted therapeutic effectiveness—For example, finding new and effective benefits for a product, identifying new indications, assessing the optimal doses of approved products, etc.
- Better understanding unique populations—Identifying if a special population, such as elderly, pregnant, or pediatric patients, could benefit from a product, while also enabling better understanding of effectiveness in patient sub-populations.
- Fulfilling post-marketing requirements—Such as committing to RWE analytics after approval to further understand the product's benefits
- Enhancing the label—Being able to better inform patients and healthcare practitioners of important information not included in approved indications such as adding benefit/risk information from observational studies.

7. Prepare for Submission Early

Regulatory submission isn't a surprise element, so why don't more device studies start preparing early for submission? Medical devices have unique regulatory pathways so proactively planning for them can greatly impact your overall trial timelines.[14]

The device class and approval pathway have a major impact on the average wait time for the FDA medical device approval process. But there are still things companies can do to control their device's time-to-market.

- It's never too early to begin preparing for successful submission. Start by prioritizing pre-validated vendors that support integrated and effective document management practices.
- You can't control the FDA's response time to an application, but you can control the speed and quality of your application using right-sized technology for medical device companies.
- Identify vendors that have workflows to support document control, unified data management, design controls, risk management workflows, and end-to-end visibility.
- Every major market in the world has its own set of regulatory requirements. If you are planning to launch somewhere besides the US or EU, you will want to fully understand the requirements in those regions. Using technology with pre-built compliance will help maintain quality management automatically.

In Conclusion

For the immediate future of medical devices, it seems speed-to-market paired with product innovation will continue to be the leading competitive drivers. Medical device companies will need to look for ways to eliminate redundant workflows, increase operational efficiencies, increase data visibility, and eliminate excess costs wherever possible. Having the right vendors on-hand will be pivotal to hitting these benchmarks.

Medrio has helped more than 180 device organizations right-size their eClinical technology to achieve regulatory approval. Reach out to learn how Medrio's integrated solutions will help your medical devices get to market faster.

About Medrio

At Medrio, we know that it takes a global village to achieve a healthier world. Our leading eClinical Data solutions have helped sponsors, CROs, and sites from all trial phases and therapeutic areas secure over 375 regulatory approvals. Whether conducting traditional, hybrid, or fully virtual trials—our adaptive platform of EDC, DDC, eConsent, RTSM, and ePRO/eCOA help streamline your studies, without compromising data quality. And our experts are on-call 24/7 to help you solve your most pressing needs. Discover the Medrio difference and learn more at medrio.com.

About The Author Tina Caruana

Tina is a clinical trial innovator with over 20 years of experience in Clinical Operations. She has worked in big pharma, small biotech and CRO organizations, managing Phase I-IV global trials across multiple therapeutic areas. Tina has expertise leading remote, home health trials – decentralized, home-based, hybrid trials conducted around the world. She also serves as an IRB Board member, routinely reviewing drug and medical device trials with a focus on regulatory oversight, research ethics and human subjects protections.

Tina currently serves as the Subject Matter Expert at Medrio for eClinical Solutions.

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