MEDIDATA

WHITE PAPER

Trailblazing the Medical Device Trials Landscape:

Experts Share Insights on Industry Challenges and the Value of Choosing the Right Technology Provider

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Introduction

Medical device clinical trials face unique challenges compared to traditional drug trials, particularly in the context of the rapidly evolving landscape of medical device innovation coupled with increased regulatory complexity, mounting cost pressures, and the shift towards value-based care. These challenges are further exacerbated by the ongoing consolidation of hospitals, which is fueling greater price transparency and the need to demonstrate outcomes benefits. The industry is also contending with escalating manufacturing costs, supply chain challenges such as raw material and semiconductor chip shortages, and a shortage of skilled workers.[1]

To navigate these dynamics, the MedTech industry is transitioning from hardware-focused to software-focused solutions[2] with Healthcare information technology (IT) playing an important role in this transition, accounting for a significant portion of new medical device trials.[3] These include product development in areas such as remote monitoring, sensor technology, applied analytics, and surgical robotics. Also widespread are clinical studies in the cardiovascular field (e.g., valves, leadless cardiac implantable cardiac rhythm management devices, stents) and neurology (e.g., spinal cord stimulators).[4]

While a large portion of medical device studies is conducted in North America, Europe (primarily Germany) and Asia (especially China) also contribute significantly. However, the recent implementation of updated regulatory requirements in the European Union, known as the Medical Device Regulation (MDR), **has triggered a shift away** from Europe. This shift underscores the evolving dynamics and challenges within the industry, possibly driven by the recent EU Medical Device Regulations.

To ensure that manufacturers and contract research organizations (CROs) can successfully maneuver through evolving challenges and gain acceptance from regulators, payers, and patients, clinical trials must advance in lockstep with those innovations. After all, the key factor that can secure devices' marketing approval, market adoption, and safe use is valid and reliable clinical evidence.

This white paper offers a glimpse into a series of insightful interviews with decision-makers in the medical device industry representing a variety of therapeutic areas. A third-party vendor recruited the experts and conducted one-hour interviews in November/December 2022. Participants were blinded to the research sponsor and received an honorarium for their time.

The objective was to develop an understanding of their perspectives on medical device clinical trials and where they see the greatest challenges and opportunities in the industry including industry-specific pain points, key considerations for selecting a clinical trial solutions vendor, insights into the customer buying process, and thoughts on key technology areas for the future. In addition, these insights are complemented by additional market research findings and secondary research, including a separate market research study conducted with the Society for Clinical Research Sites (SCRS) focused on sites' perspectives of unified platform solutions, and internal customer interviews.

Findings

The following sections summarize the key insights derived from the interviews, complemented by a contextual industry-specific discussion.

MEDICAL DEVICE INDUSTRY-SPECIFIC PAIN POINTS

The major pain points identified in the interviews with industry participants are as follows:

1 **Keeping up with rapidly evolving and complex regulatory requirements across different jurisdictions**

"The biggest pain point for me is working with Regulatory to understand exactly what are the requirements … Who's going to help us use some frameworks to drill into the complexities and get to some solutions and answers quickly?"

2 **Outdated regulatory documentation systems, characterized by manual and siloed processes, hindering efficiency and impeding streamlined operations**

"Checking the case report forms against the source documents. Regulatory binders are a pain point … If that could all be electronic and easily done, then that would be great."

3 **Adhering to global and local requirements for patient privacy and ensuring robust cybersecurity measures**

"Privacy regulations, such as GDPR, are a huge challenge, and they don't align with US or other country regulation requirements for data capture, data storage … Same thing in China … If you have a product for global launch … where the studies need to be executed, where the data needs to remain or can go legally."

4 **Demonstrating product value through specific economic endpoints, such as cost-effectiveness analysis, becoming a critical aspect that requires careful planning and execution**

"I think value-based mindset and outcomes-based data, economic endpoints in the medical device world is like the holy grail … because that is where we fail…"

5 **Ensuring site satisfaction and engagement, which cannot be understated, and implementing new tools and approaches that facilitate improved communication, collaboration, and support for trial sites (key to increasing their satisfaction and engagement levels)**

"From a site perspective, what we often hear is their frustrations with different logins, different accounts, different usernames or passwords, different timing out, having to switch from one system to another even within a manufacturer or sponsor…"

DISCUSSION

A recurring pain point among respondents was the challenge of ensuring regulatory compliance within a rapidly evolving global landscape. This is exemplified by the 174-page update to the European Union's Medical Device Regulation that came into effect on May 26, 2021, and provides an extensive set of new regulations that govern production and distribution. Moreover, regulatory authorities worldwide regularly publish updated guidelines and regulations aimed at achieving greater standardization, enhanced postmarket surveillance requirements, process-oriented risk management, and an approach that considers the entire life cycle of medical devices. Successfully navigating these changing regulations is important to ensure new devices meet the necessary compliance standards and benchmarks for safety and efficacy.

Similarly, as artificial intelligence (AI) and machine learning in new medical products continue to outpace current regulatory frameworks, regulators, such as the Food and Drug Administration (FDA), periodically issue plans and discussion papers to advance their frameworks tailored to these technologies. For instance, in 2021, FDA released **Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan**. This was followed by a May 2023 discussion paper authored by FDA's Center for Drug Evaluation and Research, in collaboration with the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health, intended "**to communicate with a range of stakeholders and to explore relevant considerations for the use of AI/ML in the development of drugs and biological products.**" By working with thought leaders in the field and actively engaging with regulatory authorities, medical device manufacturers and CROs can ensure that new devices are developed so as to prioritize compliance, safety, and efficacy.

Ensuring privacy was identified as another major challenge. State-of-the-art medical device trials continue to increase in complexity and collect large volumes of personal patient data, protected health information, and personally identifiable information. This rapidly evolving environment has created challenges, including how to achieve effective data oversight and accountability to ensure that privacy and security comply with the relevant laws and/or are consistent with issued guidances, such as the Health Insurance Portability and Accountability Act (HIPAA), EU General Data Protection Regulation (GDPR), and FDA guidances. Adopting modern trial platform solutions can provide assurances for privacy. For instance, the backbone of Medidata's technologies is a modern and exclusive Unified Protection Strategy (UPS), which unites information security, data privacy, and quality management expertise under a single operational umbrella. These three pillars work in unison to safeguard trial data and ensure regulatory compliance.

Moreover, deploying modern technological solutions can effectively help navigate the other identified pain points. For instance, unified platform solutions that provide real-world data as comprehensive patient profiles can be instrumental in developing value-based endpoints while also fulfilling post-marketing obligations. User-friendly and unified clinical trial platform solutions can also facilitate the seamless connection between siloed processes and provide innovative tools that can enhance site satisfaction. **A survey by the SCRS** showed that 46% of sites wanted integrated and consistent technology to support their trials, particularly decentralized clinical trials and that a third of sites would save 10+ hours per week by using a single clinical trial system. Furthermore, our research consistently shows that sites are often frustrated with having to deal with different systems and system requirements within the same study. For instance, 67% of sites are currently using six or more clinical trial technology systems, with too many logins, and training to complete, topping the biggest challenges with sites' clinical trial systems.

By embracing the right tools and strategies, the medical device industry can navigate these pain points to continue to foster and drive medical advancements for patients.

THE IMPORTANCE OF UNDERSTANDING MEDICAL DEVICE TRIALS AND THEIR DISTINCT CHALLENGES

Compared to drug clinical trials, the medical device industry faces distinct challenges, such as differences in terminology, inherent uncertainty and unpredictability associated with potential device implant procedures and performance and outcomes, and commitments to long-term post-marketing surveillance. As demonstrated in their responses, respondents emphasized the importance of working with partners that understand medical device trials and their unique challenges.

1 **Technology providers often use terminology that is highly specific to drugs, but the information required for devices differs significantly.**

"Vendors use terminology specific; indications, medical history ... that seems to be very much pharma focused"

"There are specific files/ specific information that needs to be filed appropriately and the requirements for drug trials are different from the requirements for device trials, I think it would be nice to have a vendor that understands those differences" (e.g., eTMF)

2 **Medical device trials typically involve a smaller number of patients, making them susceptible to challenges such as limited statistical power, reduced generalizability, increased variability, and several biases.**

"Med device side ... fewer studies. They are often post-market. The number of subjects is smaller..."

3 **As compared to drugs, medical devices may undergo many more modifications or iterations during the trial, which can introduce variability and impact the integrity of the study. Managing changes to the device while maintaining data quality and consistency is a unique challenge.**

"We are in MedTech, you're, you're always expecting there's going to be a change on the MedTech side, whereas for pharma it is unusual to have that much change"

4 **There is more required patient support when recruiting for medical device trials due to highly specific eligibility criteria, the requirement for invasive procedures (in some instances), and heavy reliance on physician referrals.**

"Device trials can sometimes be more challenging to enroll. ... There's troubleshooting that goes along ... the trial ... it can sometimes be a challenge"

"Patient recruitment ... it requires more analysis, more assessment, and more support also for the hospital to pick the right patient, versus a potential standard drug study"

As compared to drug clinical trials, medical device trials have distinct needs and challenges. Respondents underscored the importance of collaborating with vendors experienced in medical device trials, as they possess the expertise to serve the specific needs of these studies, and better navigate their unique challenges.

KEY CRITERIA CONSIDERED WHEN SELECTING A CLINICAL TRIAL SOLUTIONS PROVIDER

When selecting a clinical trial solutions provider, respondents identified the following key factors:

1 **The industry is cost-sensitive, so accurate and transparent pricing is important. When possible, the cost of accommodating study changes should be provided upfront.**

"The other thing that rubs me the wrong way ... is the change orders. ... either build two change orders into your contract or better vet what change orders are going to cost and what is a change and what is not."

2 **Site endorsements, if available, and quality of service both play a significant role, and effective communication and a partnership mindset are also important factors.**

"I asked the sites what vendors they used for an EDC... That's what was really important to us..."

3 **As trials expand their global footprint, a global approach is becoming more important.**

"Having a global approach is really important for big companies. So how does that system work with different languages? You've got customers and users all over the world, so what languages are offered and supported here? What keyboards and things?"

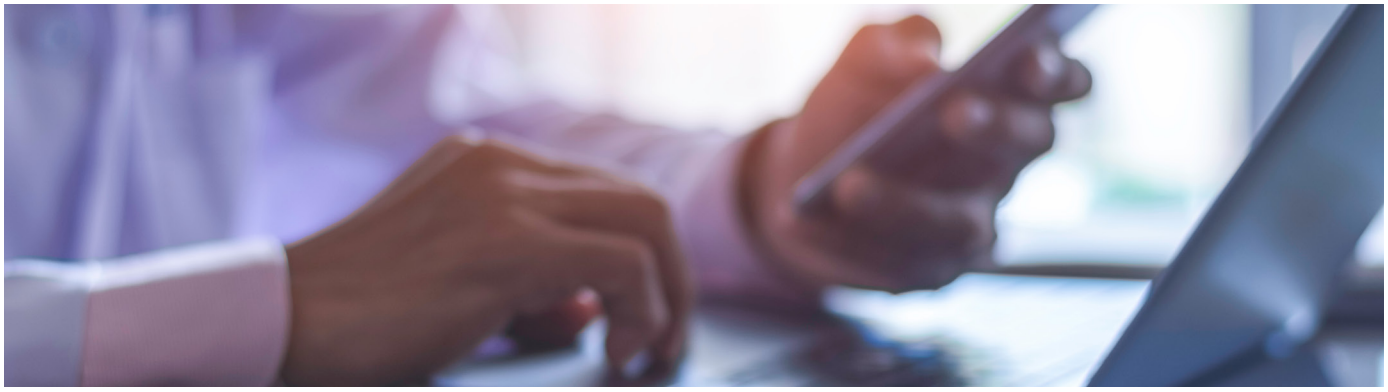
4 **The availability of proven end-to-end solutions with offerings that work together and originate from the same company.**

"Get into the clinical trial from an end-to-end perspective. You need to understand the documentation as the first step and study closeout and reporting with the definite eye on outcomes data as your endpoint ... One umbrella solution..."

5 To ensure the success of modern device trials, it is important to employ solutions that encompass the entire spectrum from data to knowledge to application. This includes data accessibility, interoperability, automation, and application.

"Data hygiene, data structure, data harmonization, and most importantly data Interoperability is a concept that people want"

"I like to call it from information to knowledge to applications. So there needs to be not just an information database mindset, but you will have to translate it into knowledge so that the sponsors can then take the knowledge and find where to apply it proactively."



DISCUSSION

When it comes to selecting clinical trial solution providers for medical device trials, several important criteria were identified, such as accurate and transparent pricing, and the ability to accommodate study changes and incorporate them into the pricing upfront (i.e., minimize the number of change orders).

Since device trial success is increasingly reliant on data accessibility, interoperability, automation, and application, proven end-to-end solutions have become an increasingly important determinant. One example is the Medidata Platform, Medidata's secure, stable, and scalable cloud-based unified platform that encompasses all Medidata solutions; information security, data privacy, and quality management are applied consistently across the product portfolio. This unified platform brings together all stakeholders (e.g., sites, sponsors, CROs, and patients) to improve collaboration and efficiency.

To ensure that the most suitable solution that aligns with your trial requirements is selected, it is important to incorporate a thorough provider selection process. This process should focus on identifying a solution that offers flexibility, scalability, and advanced analytics that can effectively address the challenges posed by modern medical device trials. Engaging in early discussions with trial solution experts and landing on the right solution for your study can significantly mitigate the unique challenges associated with medical device trials.

Overall, technology provider selection involves considerations such as pricing and the availability of end-to-end solutions. Other important factors include site endorsements, a global approach, and service quality.

CUSTOMER BUYING PROCESS

To win requests for proposal (RFPs), the following were identified as important factors:

1 Customized product demos that are tailored as much as possible to specific needs; the ability to try the solution before buying

"The demo is an important piece. We have seen many different demos. The one that we like the most is the one that is real with our own ideas."

"Try before you buy model; few weeks of sampling the software, the system. We would evaluate how easy is it to import, and export data? How user-friendly are the key and core features and functions? And then we would see how the company would respond when we found problems. Were they open and responsive and flexible?"

2 Present a strong team and demonstrate commitment to the long-term success of the program; responsiveness during the buying process

"The quality of the RFP is quite important, and then the responsiveness and the engagement of the vendor. If people are slow to respond or don't respond appropriately, that can have a big impact…"

"I felt comfortable with … the people that I was going to be working with in the end. That made a big difference for me." to respond or don't respond appropriately, that can have a big impact…"

"I felt comfortable with … the people that I was going to be working with in the end. That made a big difference for me."

3 Relevant experience with medical devices, including therapeutic areas, company names

"List some of the top companies that you work with, and how many years you've been working with device trials" … "I think you definitely should get down to exactly what they've got experience in."

4 A vendor with comprehensive service offerings across the clinical and regulatory spectrum

"One-stop shop for all your clinical and regulatory needs…"

DISCUSSION

When selecting technology providers for medical device trials, several important themes emerged.

These include customized product demos and the opportunity to try the solutions before purchasing. The strength of the provider's team, demonstrated commitment to long-term success, and responsiveness during the buying process were also highlighted.

Additionally, relevant experience with medical devices, including therapeutic areas and pricing flexibility, and a comprehensive solution for all clinical and regulatory needs were deemed important.

While these expert insights appear obvious, in our experience, some technology providers do not provide the specific information requested by potential buyers simply because they lack the experience that would instill the necessary confidence in their buyers. Medidata, with its team of seasoned experts, is proud of its extensive experience in the medical device space, having worked on more than 800 medical device trials and collaborated with nearly 200 different sponsors across more than 21,000 study sites.[1]

KEY TECHNOLOGY AREAS FOR THE FUTURE

The respondents provided several themes for desired future features for clinical trial solutions.

A patient feedback tool was highlighted as important to gather insights directly from patients, enhancing patient centricity. The patient perspective is playing a greater role in the success of new products and giving patients the ability to voice their opinion on how the product performs and getting that information to the FDA could be instrumental in the approval process.

Respondents also put forth a concept of an "early warning tool," which would provide timely alerts and insights to identify potential issues as early as possible. This tool could help manufacturers have a global perspective on what is happening with their medical devices beyond clinical trials and registries.

Another proposed feature was a data-to-protocol mapping tool, aiming to streamline the process of aligning data collection with study protocols to show the relationship between clinical trial data and specific protocols that were developed, which FDA often requests when it is evaluating 510(k) applications. Other ideas included incorporating bots and language recognition technology and financial predictions for better resource planning.

DISCUSSION

As medical device trials continue to rapidly evolve in their design and conduct, including an explosion in the number of data sources and data points being collected, traditional monitoring and data management approaches are no longer sufficient to meet their needs. Embracing the patient voice through patient-centric tools like Medidata's patient Insight Board and myMedidata app, alongside advanced data technologies featuring intuitive visualizations, advanced analytics, and real-time data from all sources, will enhance trial efficiencies and execution through automation. Moreover, integrated clinical trial financial management tools can further streamline processes, handling everything from budgets to payments, resulting in additional efficiencies for medical device trials.

1. This number represents the overall number of sites used, which includes duplicates.

Summary

To summarize, medical device clinical trials pose unique challenges compared to drug trials. These challenges include differences in terminology, more modifications and iterations, higher barrier for patient recruitment, user variability, longer term surveillance, and extensive data collection and analysis in an increasingly value-based reimbursement model. Significant pain points that were identified include evolving and complex regulatory requirements, data privacy concerns, and outdated documentation systems.

Moreover, price sensitivity is high in the medical device industry, and thus, device trial vendors must maintain precision and transparency in pricing, while allowing flexibility for study adjustments. Additionally, when selecting vendors, considerations such as site endorsements, a global approach, and end-to-end solutions were identified as important, while service quality, ease of communication, and cultivating a partnership mindset were also rated as highly important.

We expect that the medical device industry will continue to evolve and adapt to the increasingly complex and digital environment and increasingly move from single and fragmented point solutions to unified end-to-end platform solutions. This will ease the burden on clinical development teams and centralize data so relevant stakeholders can gain powerful insights from a comprehensive view of the data across all data sets.

To learn more about how Medidata can support your next MedTech trial, please visit this link

REFERENCES:

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