Veeva MedTech

2025 MedTech Clinical Benchmark Report

Industry Data on Improving Clinical Processes, Site Collaboration, and Data Management

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Increased demand for more clinical evidence, improved site collaboration, diversified trials, and more complex regulations are driving medical device and diagnostic (medtech) companies to simplify and streamline processes and invest in digital solutions.

Despite a desire to move to end-to-end digital solutions, medtech companies still struggle with manual processes, site management, and data integrity.

The 2025 Veeva MedTech Clinical Benchmark examines how companies are improving processes, site collaboration, data quality, and data integrity in response to these changing regulations and other macro trends impacting the industry.

Executive Summary

Clinical affairs teams across the medtech industry consistently grapple with resource limitations, manual processes, and the complexities of managing site relationships. These challenges are further compounded by evolving regulatory requirements, like EU MDR and IVDR, and global macro-economic pressures that are impacting innovation investments. In response, medtechs are taking steps to improve efficiency and trial conduct to accelerate speed to market and ultimately improve patient outcomes. However, adoption of end-to-end digital solutions is still outpaced by point solutions and manual processes.

Key findings

Current State of Clinical Affairs

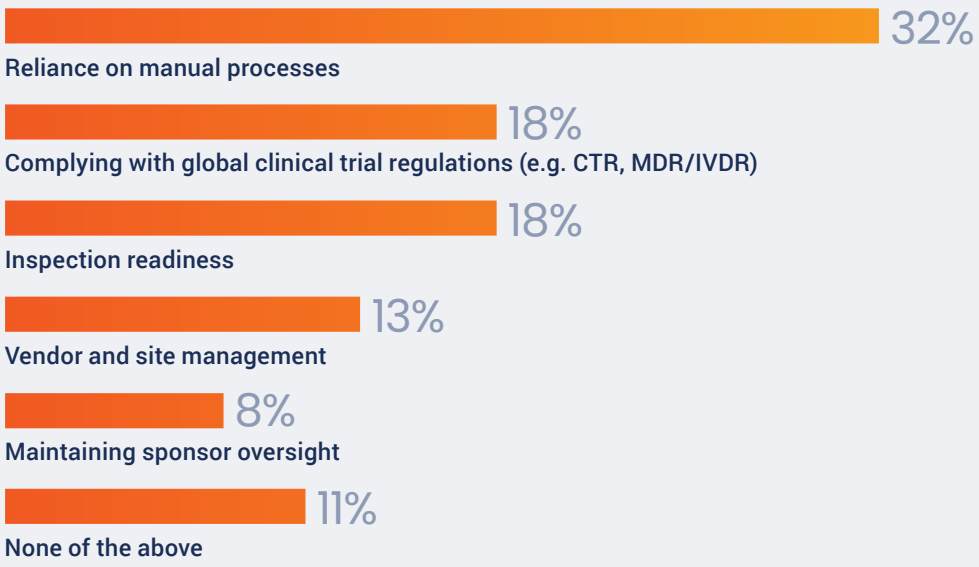
Software solutions in place to manage clinical trials

	UNDER $1B	OVER $1B
eTMF	62%	89%
CTMS	38%	72%
Site payments	21%	36%
Study training	29%	25%
EDC	62%	71%
Clinical outcome assessment (eCOA)	15%	28%
Randomization and trial supply management (RTSM)	29%	29%
Site collaboration tools	24%	14%
No dedicated applications	3%	3%

Increased adoption of eTMF (78%) and EDC (66%) systems indicates a broader industry push towards using digital solutions to increase efficiency. Having an eTMF and EDC are no longer optional; the high level of adoption across companies of all sizes highlights the fundamental role these solutions play in running a modern clinical trial. Although the adoption of core systems has increased, only 44% have eTMF, CTMS, and EDC systems all in place (and not necessarily unified or connected).

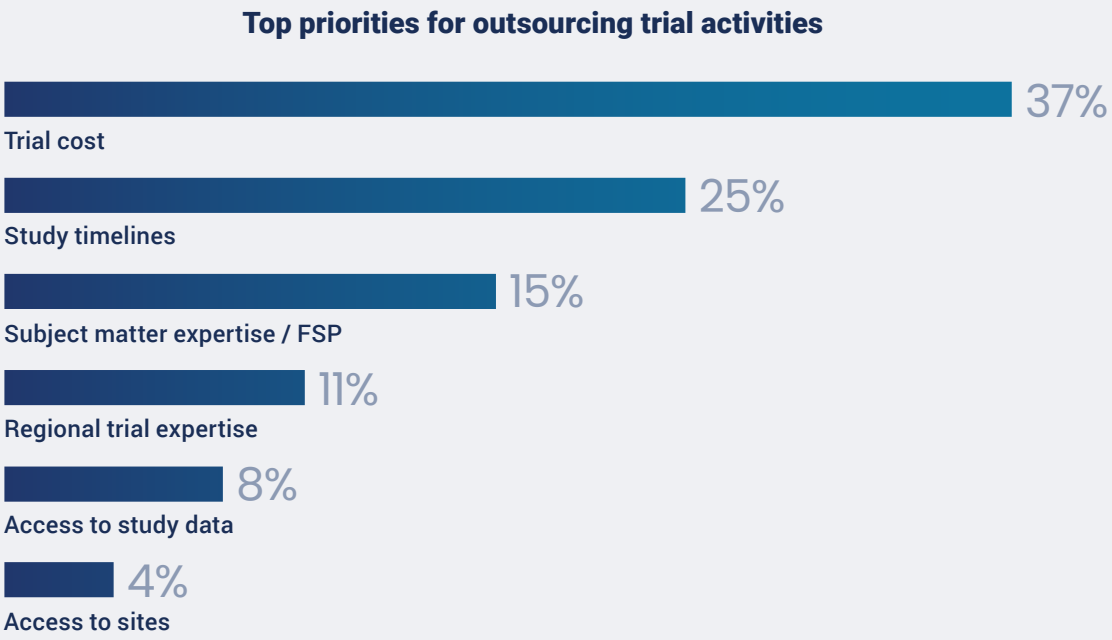
Larger companies have further enhanced their internal trial management capabilities through the use of CTMS (72%) and payments solutions (36%). Smaller companies still have room to grow, with lower adoption of CTMS (38%) payments solutions (21%), potentially due to outsourcing trial activities like monitoring. While the industry is starting to recognize value in site centric applications, adoption of payments, site collaboration, eCOA, study training and RTSM solutions, lag behind.

Top challenges related to clinical trials



The top challenge cited for managing trials was reliance on manual processes (32%), which inherently creates fragmented and inconsistent data. The lack of centralized data and access to critical documents ultimately compromises inspection readiness and audit efficiency, hindering growth and increasing cost. Regulatory compliance is another top challenge with inspection readiness (18%) and trial regulation compliance (18%).

In today's fast paced landscape, the key to accelerating breakthroughs lies in operational agility. Companies can achieve a strategic advantage by prioritizing standardization and leveraging technology to automate and streamline operations to focus on strategic projects.



The growing complexity of regulations around clinical trials creates a clear need for regional and subject matter expertise to maintain compliance. However, companies primarily outsource to cut trial costs (37%) and expedite study timelines (25%).

Even when outsourcing trials, medtech sponsors are responsible for all study data and activities. However, many times sponsors use a vendor or CRO system to manage activities, limiting their ability to track site performance, maintain oversight, and access historical site data. Providing sites access to the sponsor's eTMF and CTMS allows sponsors to better manage operational data, enabling them to monitor progress, assess efficiency, and align vendor activities to increase cost effectiveness and speed.

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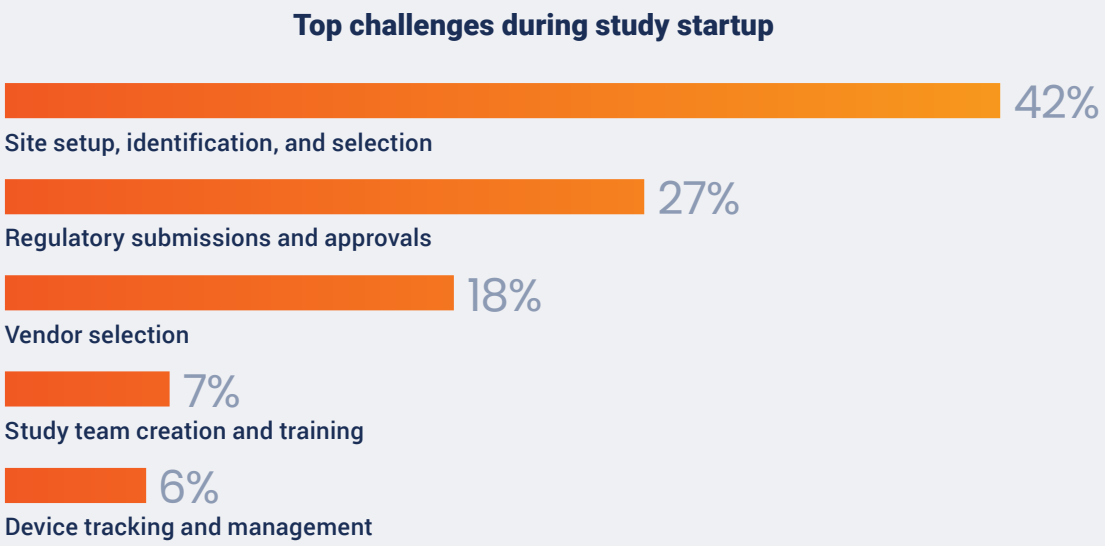
Site and Vendor Management, Data Exchange, Collaboration



Site setup, identification and selection is a resource intensive process that touches a variety of stakeholders during study startup. Medtechs ranked site setup, identification, and selection (42%) as the top organizational challenge during clinical trial startup. There is often little standardization, multiple processes, and extensive regulatory and data requirements that create additional complexity in the process. It requires significant time and effort to identify suitable sites, conduct feasibility assessments, and prepare sites to enroll patients. Delays here can cascade throughout the entire trial, affecting timelines, costs, and speed to market.

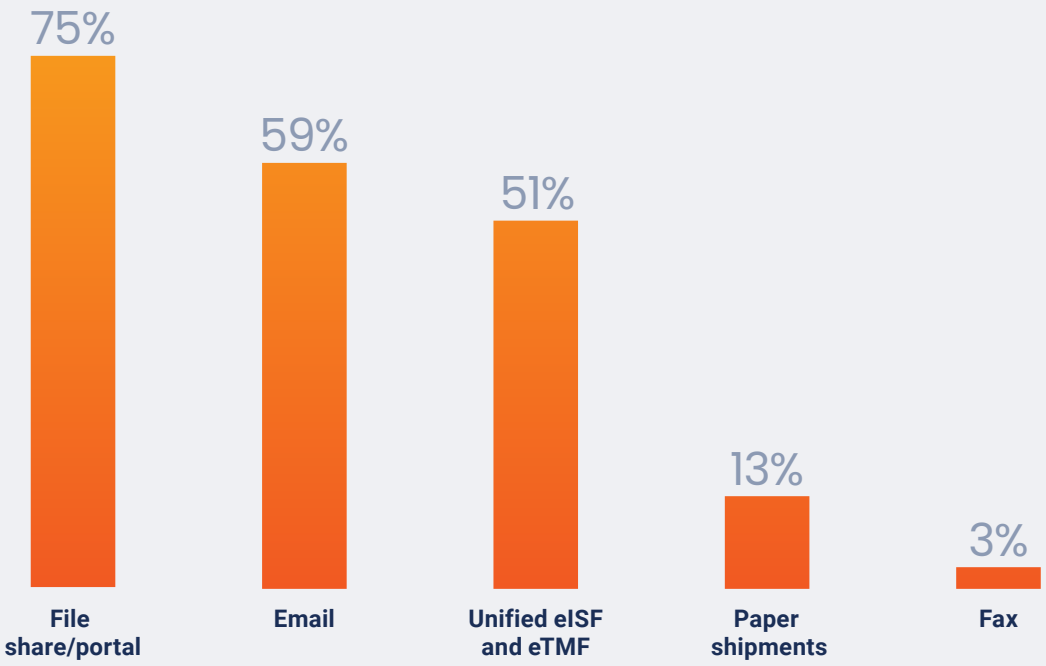
Leveraging a CTMS can alleviate site selection challenges by providing a central repository for reference and historical data on trial and site performance, allowing sponsors to identify the right sites faster and accelerate startup. Investing in a site collaboration application that is connected to the CTMS can streamline data and document exchange to help automate repetitive tasks, reduce manual effort, and eliminate the risk of data errors.

More than half of medtechs identify data as the top challenge in site collaboration, with 59% stating on-time data entry and data quality as a top three challenge and 50% stating exchange of documents and data. Monitoring and compliance (45%) rounds out the top 3 challenges and ties back to the exchange of documents and data and on-time data entry.

Higher regulatory burdens increase the amount of data and documents shared with sites. Despite the need for seamless information flow, companies are often exchanging and reviewing data and documents manually. Inconsistent data formats, disparate systems, and manual processes lead to delays, potential data inaccuracies, and increased operational burden.

Sponsors must actively compete for qualified trial sites, underscoring the importance of site satisfaction. Medtech companies can foster collaboration with sites by using digital solutions and automating processes to simplify documentation, data, and process management.

Top methods for exchanging documents and data with sites

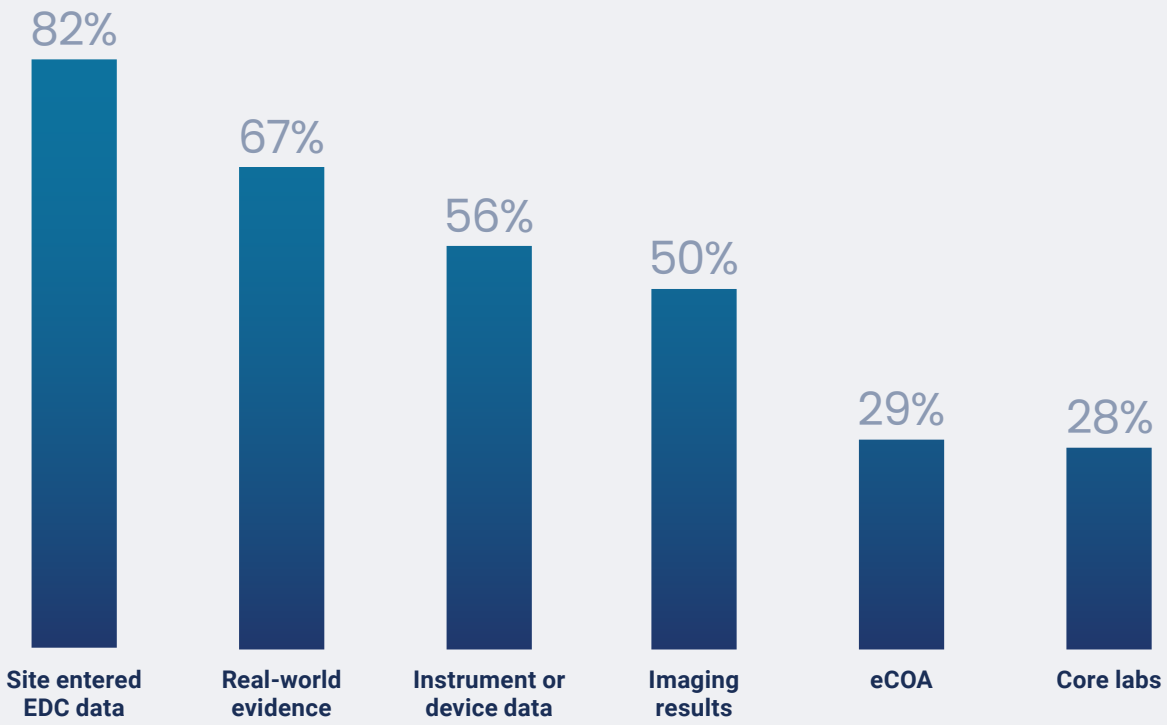


Medtech companies are still heavily reliant on file share (75%) and email (59%) to exchange trial documents and data with sites. A large portion of medtechs (46%) still rely exclusively on manual ways to exchange data through a combination of email, file share, paper shipments or fax, demonstrating a clear need for technology to improve collaboration between sponsors and sites.

Unique site requirements and technology limitations continue to pose a challenge. However sponsors are more commonly adopting digital solutions for document exchange, driven by the compelling need to reduce burdensome manual processes with sites. To foster collaboration, sponsors should focus on making it easier for sites to embrace and use purpose-built solutions that address critical pain points like training redundancies and disparate systems to ensure better site enablement.

Leveraging technology that unifies eTMF and eISF management empowers sites to have flexibility and control over their processes while facilitating access into your ecosystem. This streamlines collaboration between study team members and sites regardless of how a site operates.This digitization strategy allows sponsors to maintain compliance while remaining the sponsor of choice.

Primary data sources for clinical evidence generation



The majority of medtechs (82%) identify site entered EDC data as the most prominent source for clinical evidence generation, dispelling the recent concerns of the death of site entered EDC data. Real-world evidence (67%) is also becoming increasingly important as medtechs place a stronger emphasis on patient-centric clinical trials.

The strong desire to adopt real-world evidence and instrument or device data indicates a move beyond traditional trial data to more holistic patient insights and product performance. As the number of data sources for evidence generation continues to grow beyond EDC, data managers need a centralized system to aggregate, clean, and transform data.

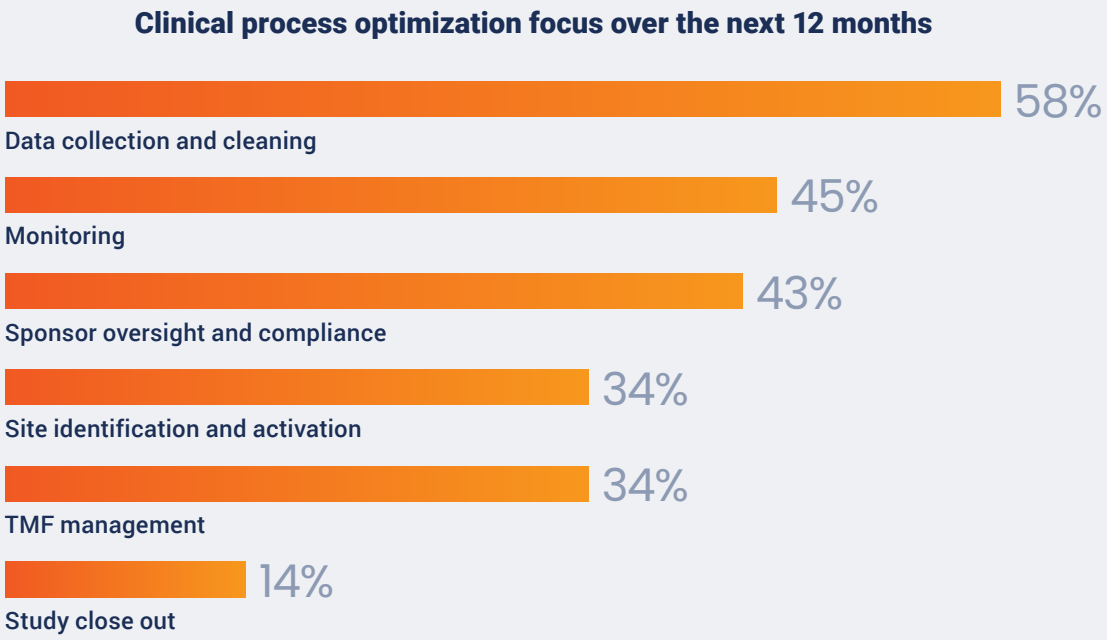
Top risk of non-compliance related to study and protocol training

While initial training is often well-managed, maintaining compliance with ongoing training, especially with protocol amendments or regulatory updates, is a significant challenge. When considering the processes most at risk for non-compliance, 38% indicated up-to-date training throughout the trial as the top concern, followed by managing protocol and regulation changes at 28%.

Sponsors struggle to manage and distribute dynamic information, sometimes across a geographically dispersed and resource constrained workforce, creating significant hurdles to keep study teams adequately trained.

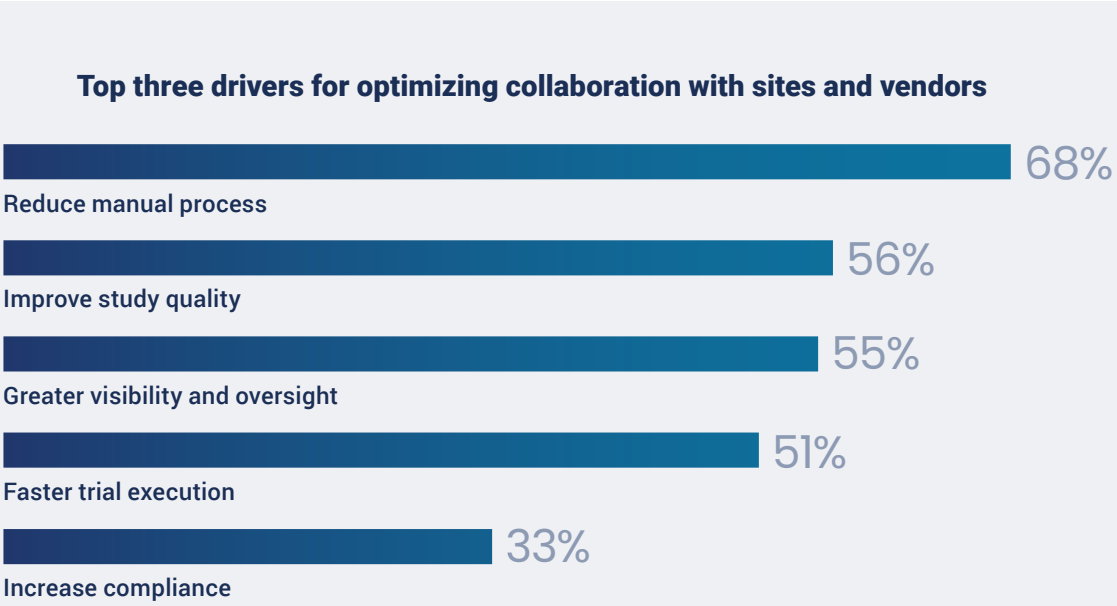
Training for protocol and regulation changes must be executed quickly to prevent delays in study timelines and compliance issues. Medtech site training is even more complex due to the added product, device, and procedure training. Training challenges are further compounded by regulatory requirements to maintain up to date training logs, as it is often a manual process that is difficult to manage across a high volume of sites. Optimization in this space can quickly provide tangible benefits to all stakeholders. By unifying learning management and clinical operations, companies can more easily manage protocol changes, role-based training requirements, and automate filing training certificates for ongoing inspection readiness.

KPIs and Optimization Priorities



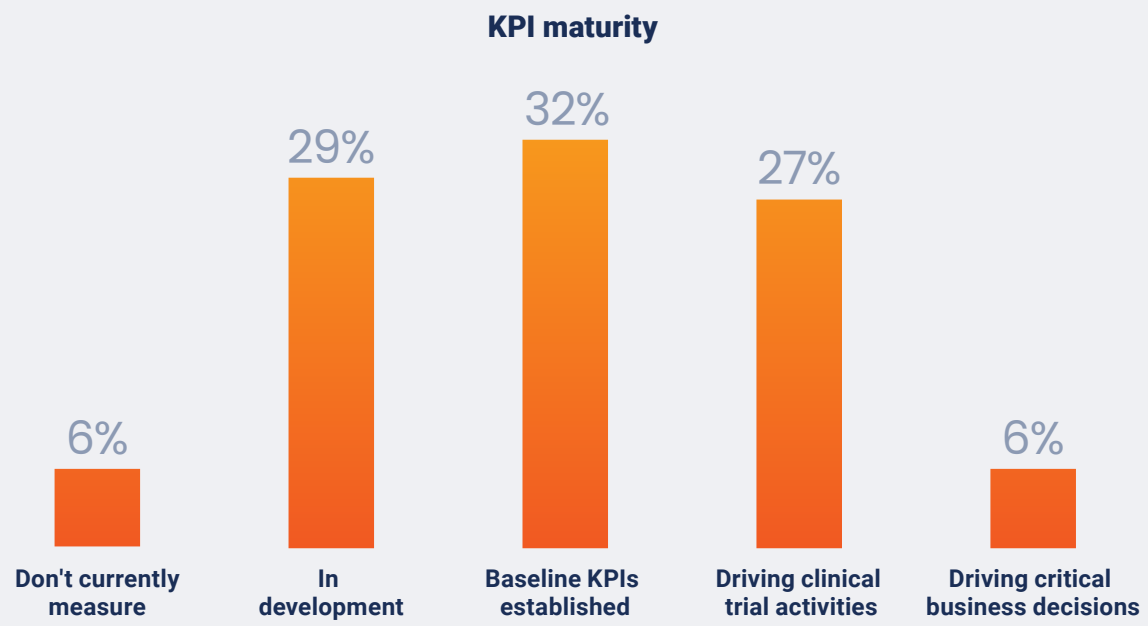
Data collection and cleaning (58%) was most consistently selected as a top 3 priority. An inefficient data collection and reconciliation process can directly impact data integrity, trial timelines, and cost. Digital but disconnected systems and cumbersome processes increase the resources required for data quality checks, manual reconciliation, and other data cleaning efforts. This directly impacts trial cost as monitors and data managers will spend more time verifying and reconciling discrepancies, diverting their attention from other trial oversight activities.

Clinical organizations should optimize digitizing and centralizing through technology as a strategic imperative to connect all data-generating activities throughout the trial lifecycle. This allows sponsors to unlock accurate reporting and reduces data duplication and manual transcription errors. It also improves the site and patient experience.



Reducing manual processes (68%) is the top driver indicated to improve collaboration with sites, followed by improving study quality (56%) and faster trial execution (51%), which can be directly linked to improved processes.

In order to reduce the burden on sites, it is critical for sponsors to establish repeatable processes and implement systems to centralize data collection and cleaning. Reducing manual processes and integrating sites into the sponsor ecosystem helps address some of the other key challenges: visibility and oversight, trial execution, study quality, and compliance. By ensuring timely and accurate data entry into a single source of truth, sponsors can more easily manage sites, consolidate and report on data, and close out studies faster.

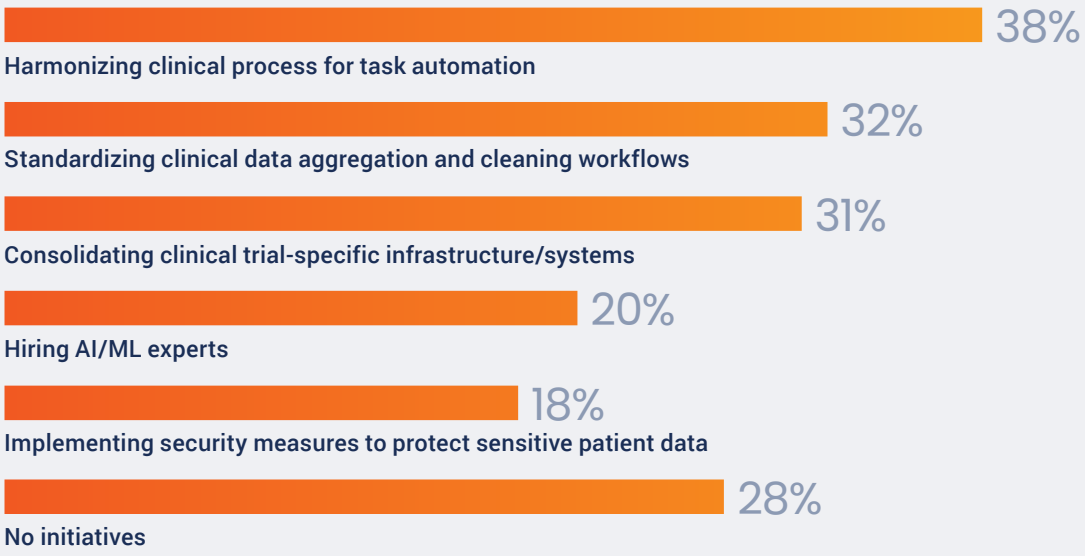


KPIs are clearly being used as operational tools to guide day-to-day activities and to establish performance benchmarks. The majority indicated that they currently have KPIs in place (65%), but only 27% of those have KPIs to drive clinical trial activities and a mere 6% have KPIs driving critical business decisions, the remaining 32% have baselines established.

The fact that 29% are in development suggests ongoing efforts to develop KPI frameworks, showing significant room to optimize for higher-level strategic decision-making. However, developing KPIs that accurately quantify the value of a digital transformation can often be challenging to establish, particularly when relying heavily on unstandardized manual processes and disparate systems.

Developing a long-term clinical strategy around which KPIs will have the biggest influence on trial activity and critical business decisions will help improve trial conduct. In addition to influencing clinical strategy, KPIs are important elements to make the business case to assess resource and technology requirements. Companies should define a plan for maintaining their KPIs for ongoing improvement and continued value realization.

Investing in AI/ML solutions



30% **Prioritize AI/smart automation integration to optimize clinical data collection and connectivity.**

A significant portion of medtechs are not yet actively investing in the underlying infrastructure (28%) suggesting that the industry is still in the early stages of AI/ML adoption. For those that are investing in this type of digital transformation, the focus is pragmatic: automating existing processes and standardizing data to make it AI-ready, rather than purely experimental AI development. Having quality, process, and digital tools in place will enable further investment and maximize the potential of AI/ML.

Medtechs should focus on an AI/ML strategy that integrates with existing systems and workflows, aiming for iterative improvement as it becomes more established within the industry.

Conclusion

The medtech industry is actively striving to modernize clinical trial operations through digital transformation. The overarching themes reveal a pressing need to overcome persistent manual processes, strategically implement and measure the value of new technologies, foster stronger and more efficient site collaborations, and thoughtfully build the foundational infrastructure for the future. Addressing these interconnected challenges will be paramount for accelerating innovation and improving patient outcomes in an increasingly complex global landscape.

The consistent identification of manual processes as a key issue in various aspects, including site collaboration and data exchange, demonstrates a fundamental operational hurdle that digital transformation aims to address. Investment in AI/ML can supplement digital transformation efforts to help mitigate the challenges caused by overreliance on manual processes.

Investing in technology is becoming increasingly essential for companies looking to stay competitive. Companies should be strategic when developing their technology adoption roadmap, or they run the risk of finding themselves with a cumbersome ecosystem, making it difficult to gauge the true value of the investments.

Report Scope

This survey includes responses from 119 qualified respondents with clinical roles in medical device or diagnostics companies. The research consists of 14 questions, some of which included sub-questions with response metrics. The survey questions were designed for medtech professionals with knowledge of clinical processes and responsibility for clinical trial or clinical development activities within a medical device or diagnostics organization. The study also analyzed differences in data across company types and geographies. Where there were variances in data, this report highlighted them. Completion of the survey was voluntary.

GLOBAL HQ	PRODUCTS	SIZE
North America **57%**	Medical Device **68%**	Under $1B **29%**
EMEA **27%**	In-Vitro Diagnostic **14%**	Over $1B **62%**
APAC **7%**	Both Medical Device and In-Vitro Diagnostic **11%**	Unknown **8%**
Latin America **1%**	Unknown **8%**	
Unknown **8%**		