2023 Clinical Benchmark Report

Global regulatory requirements and increased focus on clinical evidence are driving medtech companies to ramp up clinical activities to maintain product marketability.

The Veeva MedTech Clinical Benchmark study examines how organizations manage clinical processes, study site collaboration, and trial data to ensure compliance and speed, as well as identifying current challenges and future priorities.

This report details insights from more than 135 clinical medtech professionals worldwide at companies ranging from small to large device and diagnostics organizations.

Executive Summary

Medtech companies are moving toward more unified and digital methods for conducting clinical research. However, resource and site constraints, point solutions, and manual processes hinder progress. There is a distinct need within the industry to streamline end-to-end clinical research while remaining compliant, and respondents seek solutions to streamline and operationalize clinical trial activities.

KEY FINDINGS

90%
regularly outsource one or more trial activities

55%
identify resources as the #1 challenge when running trials

60%
indicate issues with disparate clinical systems

83%
use emails, portals, and paper to exchange information with partners

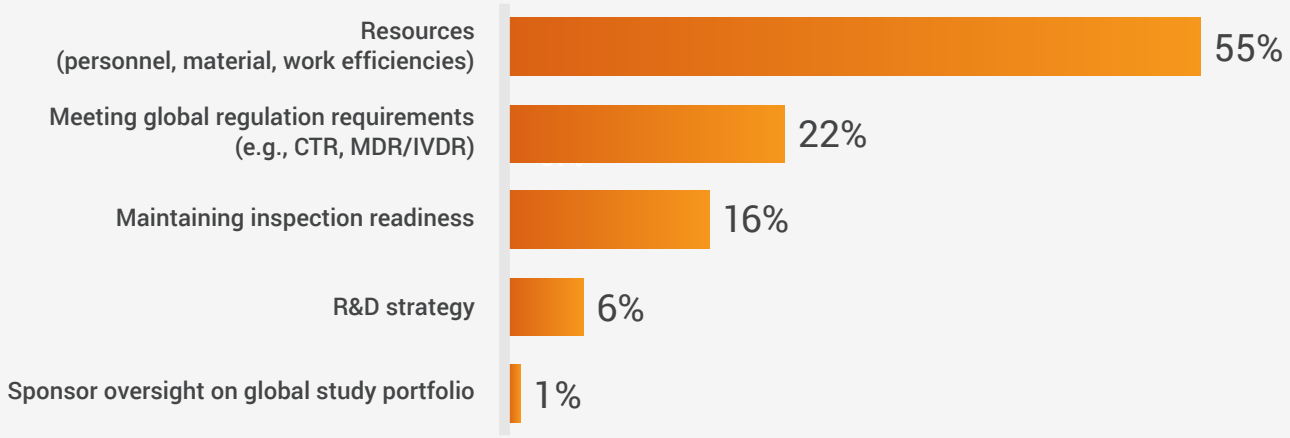
45%
prioritize full digital management of internal systems in next 12 months

Overcoming Internal Barriers

Key Organizational Challenges

55% of respondents identify resources as the key challenge when running clinical trial activities for medical device (MD) and in-vitro diagnostics (IVD) products globally. In the context of this study, resources include not only personnel but also materials and work efficiency.

BIGGEST CHALLENGES ASSOCIATED WITH CLINICAL TRIAL ACTIVITIES

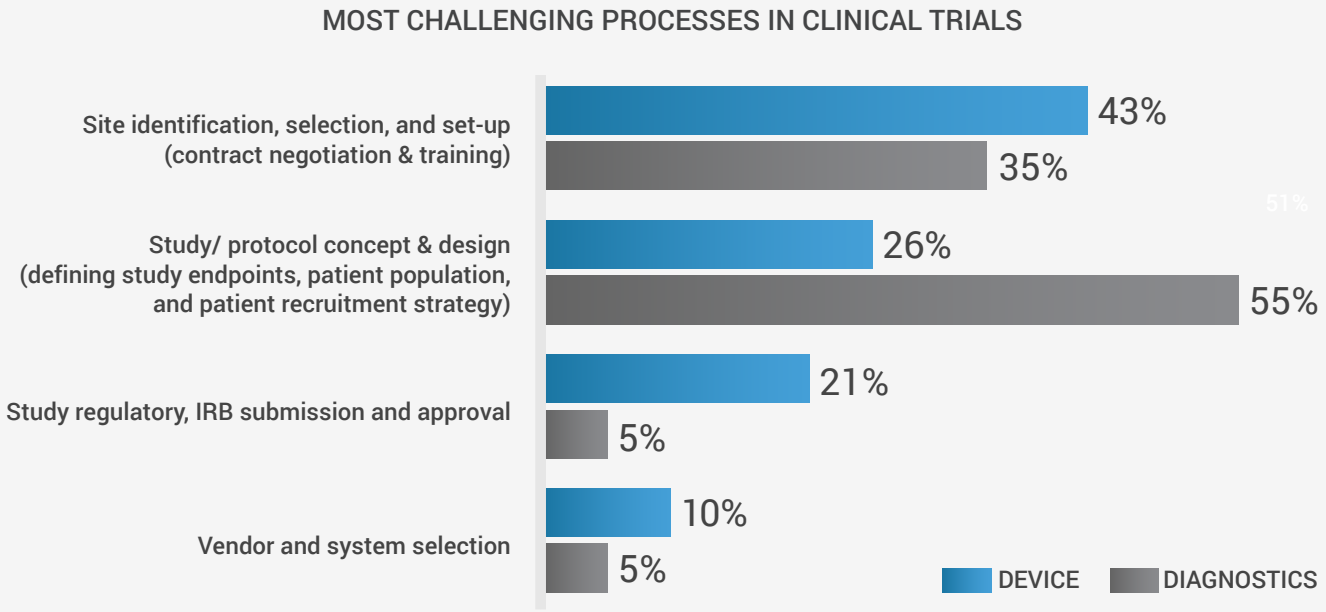


Insufficient resources can significantly impact trial conduct and delivery, resulting in poor sponsor oversight, hindered recruitment, a higher number of inspection findings, and delays. Add on new regulations like MDR and IVDR that require more clinical evidence and performance data, and the issue is compounded. All of this jeopardizes data integrity and go-to-market strategy.

Medtech organizations should complete process re-engineering to combat the resource challenge. Start by removing redundant and unnecessary activities and procedures from the end-to-end clinical process for both internal and external stakeholders. Companies should also leverage more unified cloud technology solutions that streamline and automate processes across stakeholders, partners, and geographies. These steps will improve efficiency, productivity, and compliance, and fulfill clinical evidence requirements.

Most Challenging Aspects of Clinical Trials

42% of medical device professionals cite finding and selecting research sites, negotiating contracts, and training staff as the most challenging aspects of clinical trial processes. In contrast, 55% of IVD companies identify the study/protocol concept and design as the most challenging.

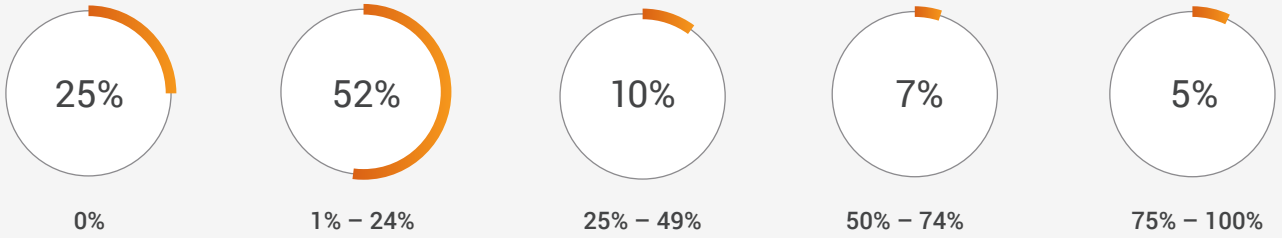


Research sites more study requests than ever before due to growing medtech demands and new regulatory requirements. For example, to fully understand new clinical evidence requirements under MDR and IVDR, sites must undergo training in standards (ISO 14155 for medical devices; ISO 20916 for in-vitro diagnostics), study protocols, and systems, which can be time-consuming and expensive. Therefore, it's even more critical for medtech companies to automate and streamline as much as possible, positioning technology as an enabler for building collaborative, long-lasting relationships with sites.

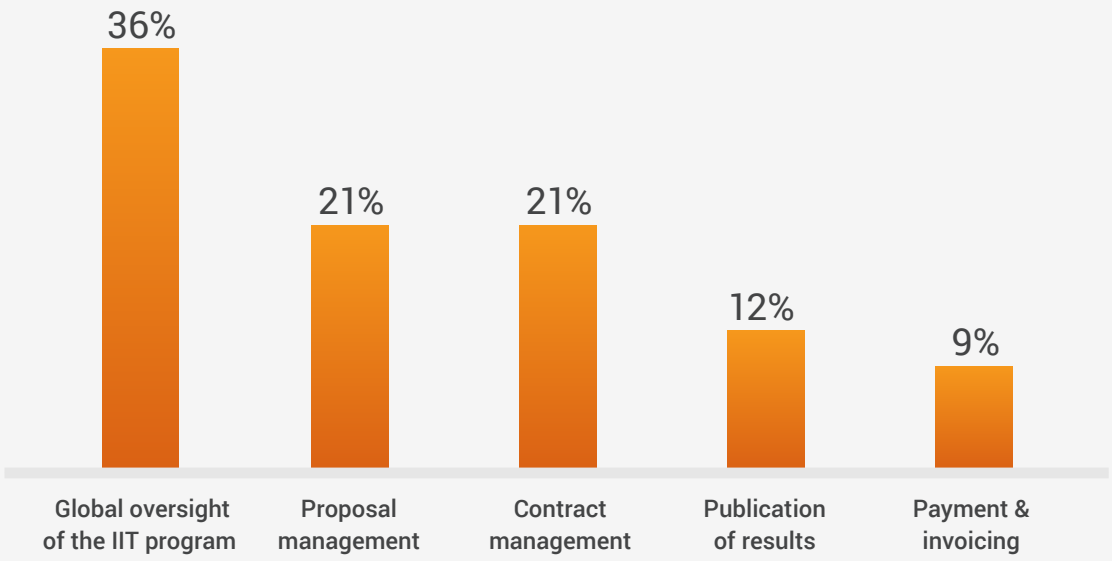
Investigator Initiated Trials (IITs)

Over 74% of respondents carry out Investigator Initiated Trials (IITs), with the majority (52%) conducting up to 24% of their global clinical trials as IITs. Additionally, 36% identify global program oversight as the biggest challenge when managing IITs, followed by contract and proposal management (21%), indicating a lack of organizational alignment.

PERCENTAGE OF INVESTIGATOR INITIATED TRIALS



BIGGEST CHALLENGES MANAGING INVESTIGATOR INITIATED TRIALS



Investigator initiated trials (IIT) are essential to clinical and physician adoption and contribute to the overall product lifecycle. Unlike medtech manufacturer-sponsored studies, IITs are initiated, conducted, and sponsored by the hospital or the investigator. As a result, manufacturers have minimal involvement and face numerous oversight challenges.

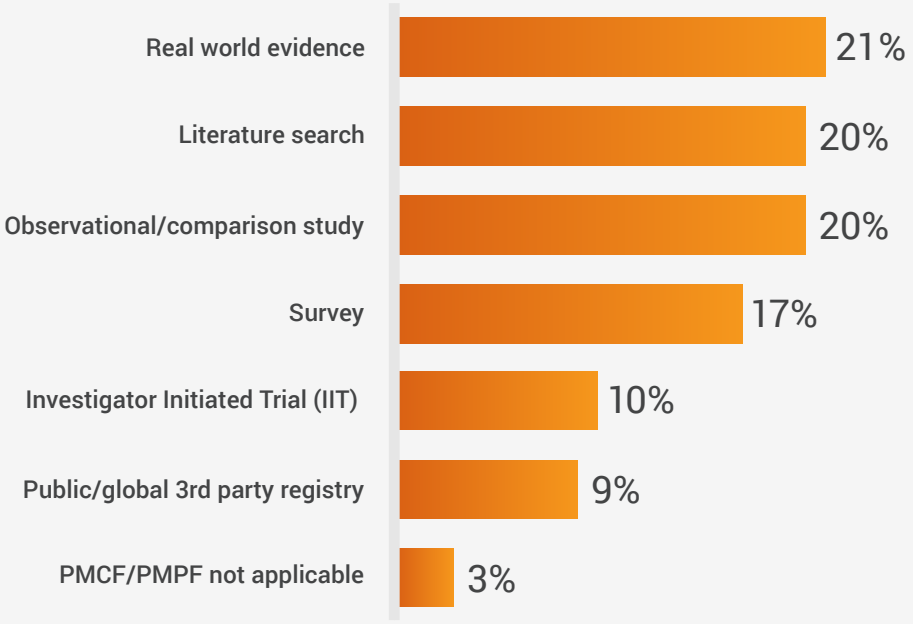
IITs also provide an essential contribution to overall clinical evidence and product performance data. To ensure investments yield meaningful results, managing IITs shouldn't be seen as a separate clinical activity. Medtech companies must create governance and oversight structures integrating IITs into their overall clinical activities.

Addressing Regulatory Changes

Post-Market Clinical Follow-up

21% of respondents use Real World Evidence (RWE), followed by literature search and comparison studies (20%) to collect information about existing products on the European market in order to comply with Post-Market Clinical Follow-up (PMCF)/Post-Market Performance Follow-up (PMPF) requirements.

METHODS USED FOR POST-MARKET CLINICAL FOLLOW-UP (PMCF)/ POST-MARKET PERFORMANCE FOLLOW-UP (PMPF)



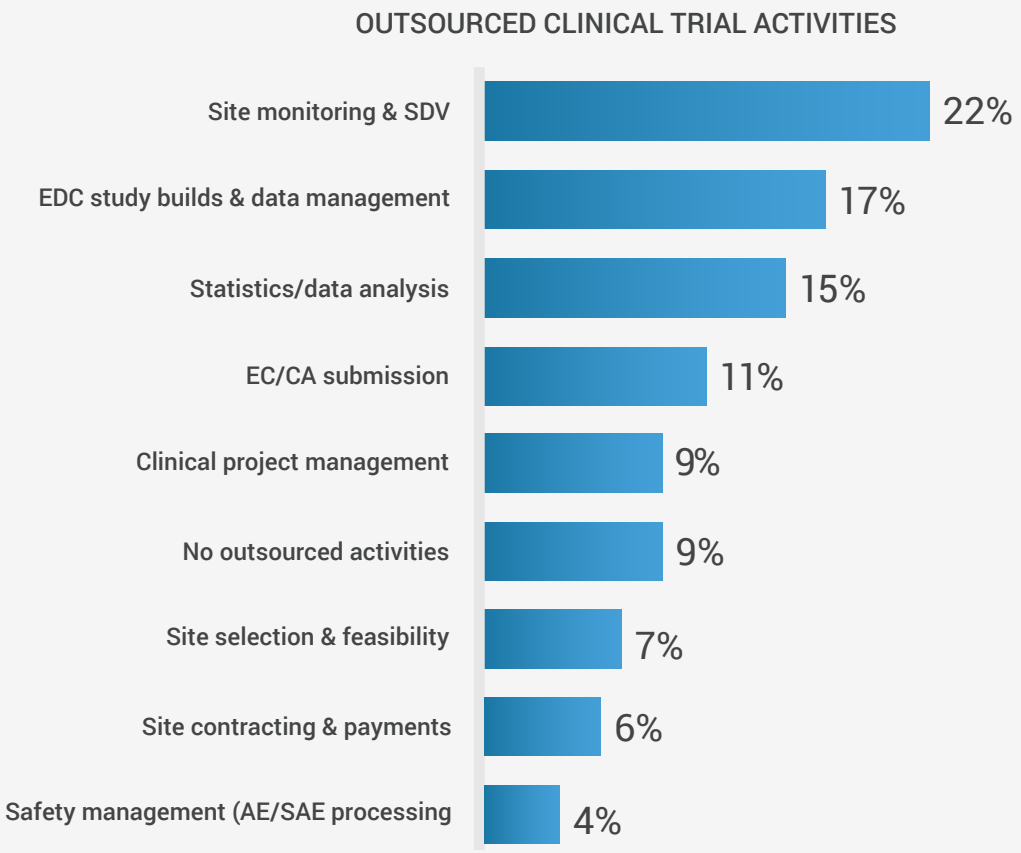
Regulatory changes, particularly EU MDR and IVDR, require manufacturers to generate more clinical data post-approval through PMCF/PMPF activities. Additionally, requirements vary greatly depending on the product class and lifecycle stage resulting in different methods for generating data.

There is no one-size-fits-all approach so it's essential to develop a strong PMCF/PMPF strategy early in the clinical plan, including an end-to-end process encompassing the entire medtech organization (clinical, medical, regulatory, quality, and marketing). This approach will allow continuous data generation throughout the entire product lifecycle ensuring ongoing oversight, compliant data, and marketability.

Building Lasting Partnerships

Working with Vendors and CROs

90% of respondents outsource one or more clinical trial activities to CROs or third parties, with the top three being site monitoring (22%), EDC study builds and data management (17%), and data analysis (15%).

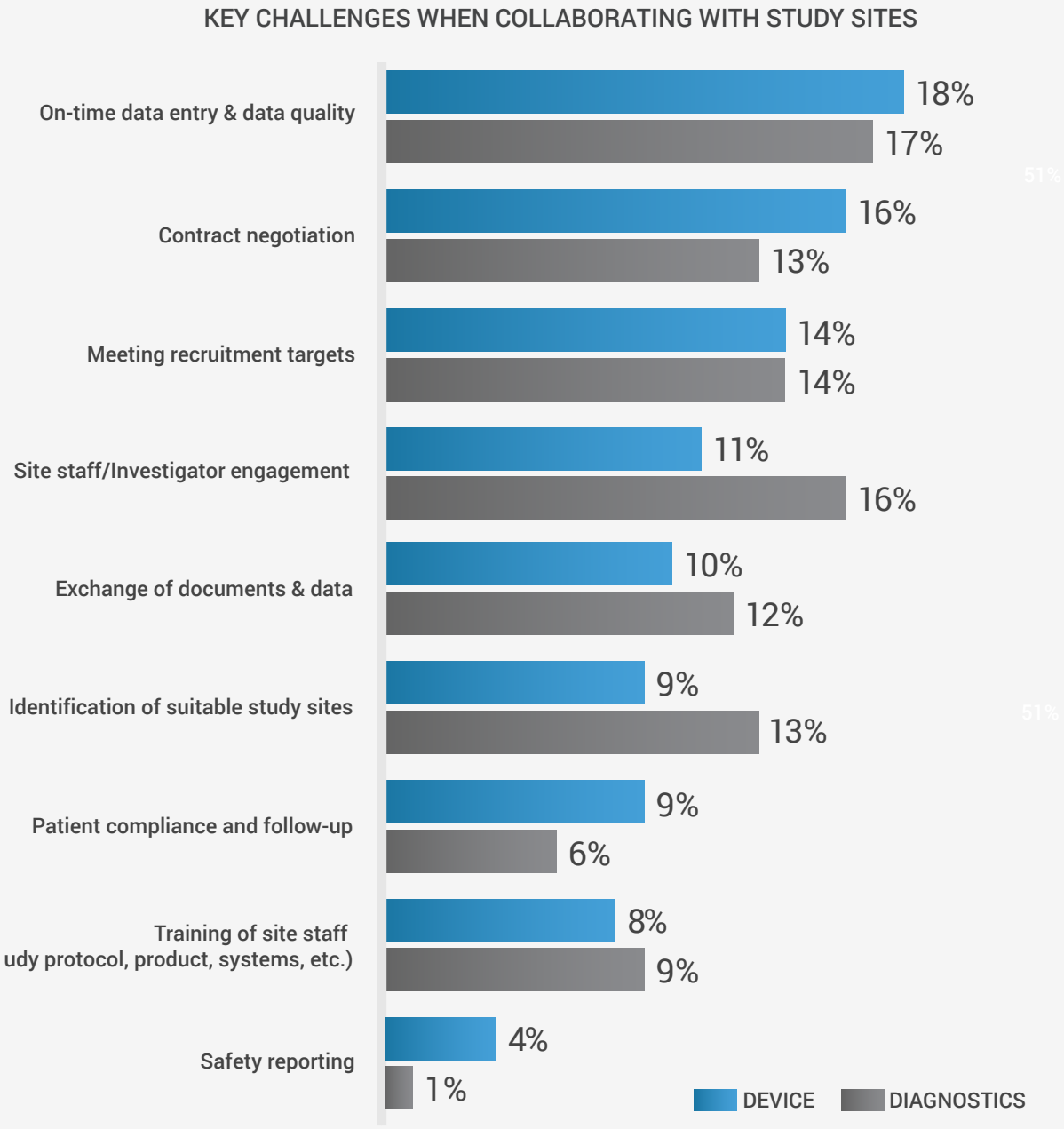


As sponsors, medtech companies are ultimately responsible for trial activities and data, even when outsourced. Without processes and collaboration, companies run the risk of redundancy and study delays.

In order to ensure compliance and timely studies, medtech organizations need systems that enable real-time collaboration, visibility, and data exchange with vendors and external stakeholders. Leveraging your own eTMF will eliminate redundant activities, reduce document duplication, remove silos, and increase inspection readiness.

Collaborating with Study Sites

For medical devices (18%) and diagnostics (17%), on-time data entry and quality are the biggest challenges when working with study sites, indicating potential delays in data delivery and study timelines. Both MD and IVD respondents' results indicate multifactorial challenges across the industry.



Well-designed study protocols go hand-in-hand with well-selected study sites to deliver compliant study data on-time. Due to global and local regulatory requirements, the number of studies required to achieve and maintain market access is increasing. In addition, medtech trials often run concurrently with pharmaceutical trials, multiplying site workloads and affecting study timelines further.

Leveraging cloud-based technology that streamlines and automates documentation, data, and processes management between sponsors and sites can reduce capacity constraints, and enable sponsors to monitor status and take corrective and preventive measures, helping to ensure compliance without compromising quality or speed.

To increase site selection success, create a scorecard that shows previous performance metrics on compliance, timeliness, quality, and recruitment. Furthermore, a comprehensive analysis of the patient population distribution across sites and countries will help achieve recruitment targets.

Exchanging Trial Data and Documents

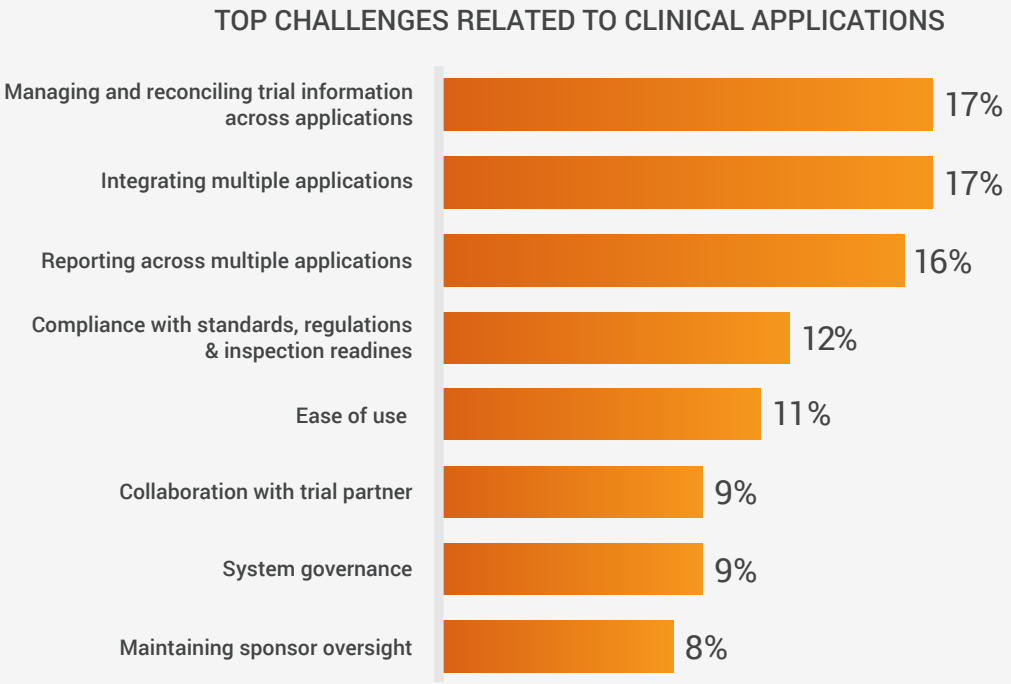
Only 17% of medtech organizations cite utilizing unified eISF and eTMF solutions for document and data management. The majority of respondents still use email (38%), share portals (36%), and paper shipments (8%), highlighting a clear need for technology to ease collaboration between sponsors and study partners.

METHODS FOR DATA AND DOCUMENT EXCHANGE WITH STUDY PARTNERS

Inefficient collaboration with sites wastes time and money. It is crucial to automate the document and data exchange with technology that meets compliance and privacy standards in order to increase efficiency and speed. Having sites leverage a single system for all trials will also increase technology adoption and success.

Key Challenges with Applications

More than 61% of respondents report having issues with disparate systems, citing systems integration (17%), cross-platform information management (17%), reporting (16%), and usability (11%) as the top challenges with clinical applications.

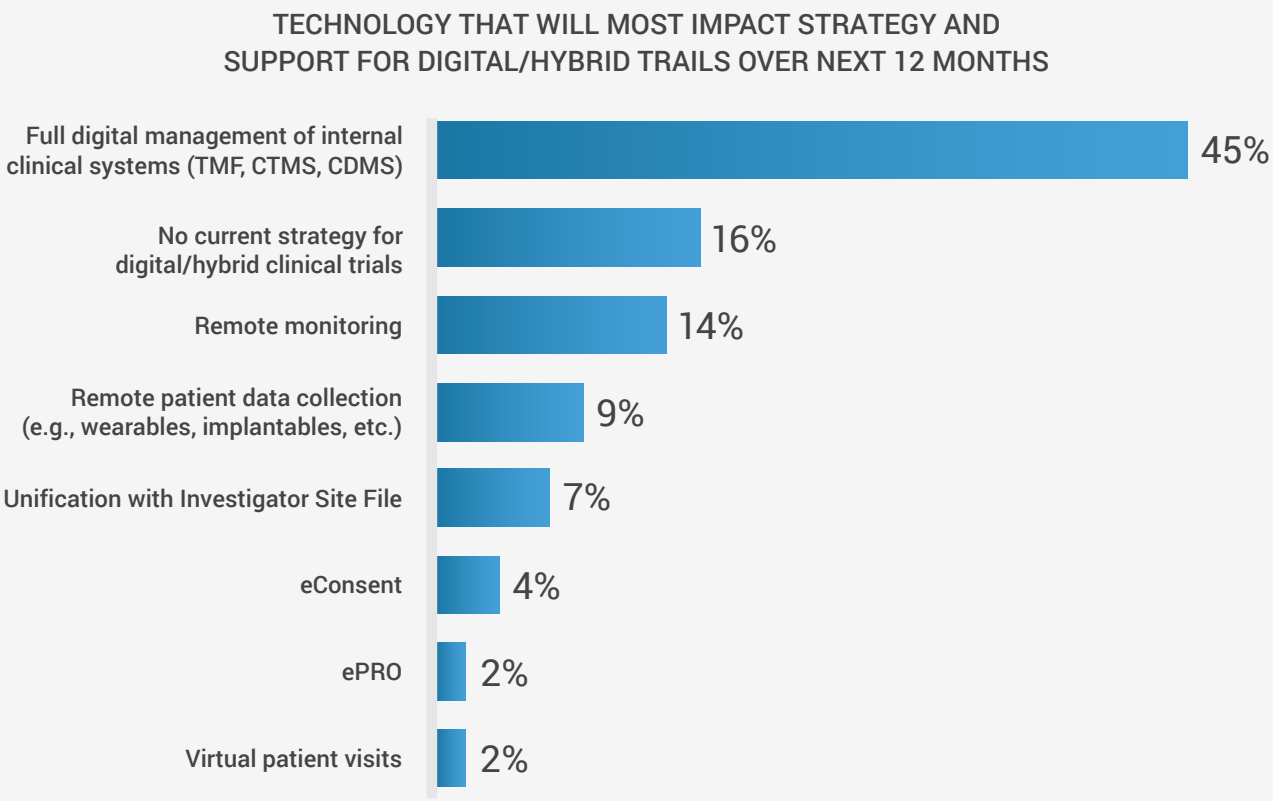


Medtech companies have various systems in-house and that only increases when working with vendors, making it even more challenging to keep track of activities, view data, and retrieve information for reporting.

Making system selection a part of the overall clinical strategy and developing a holistic approach to processes is key to ensuring scalability and speed. Driving vendor adoption is also essential to achieving efficiency and compliance. Companies should select technology that scales with business requirements, facilitates internal and external collaboration, and enables real-time data-exchange between stakeholders and vendors. This approach ensures a single source of truth, full oversight, and management effectiveness, which prevents errors and risk of non-compliance.

Near Future Technology Priorities

A majority of respondents (45%) indicate digital management of internal systems as the top priority in the next 12 months, with a further 14% citing enabling remote monitoring.

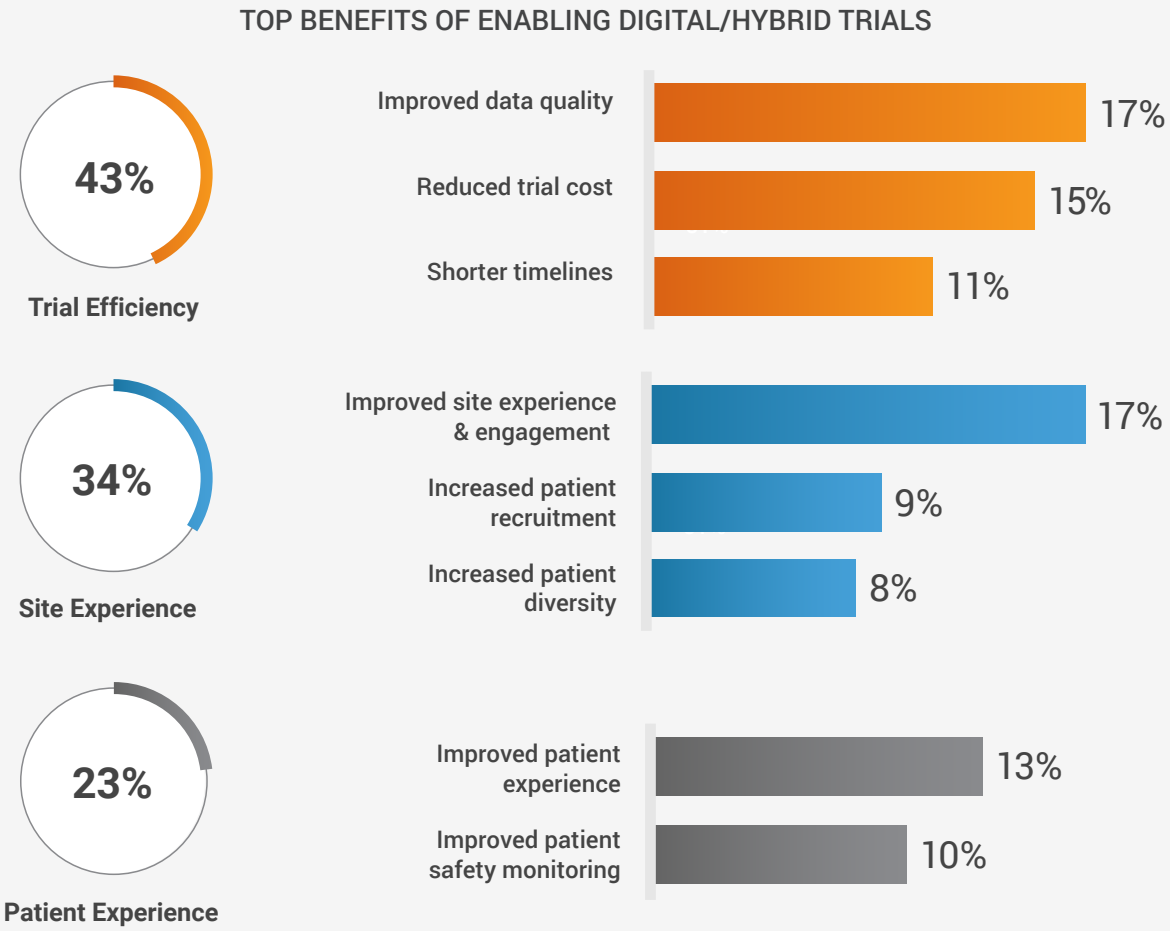


Siloed systems and processes often hinder trial success, slow execution, limit visibility, and prevent data sharing and collaboration. As organizations scale, internal systems, resources, and end-to-end processes become integral to any ongoing clinical strategy.

Whether adopting new technologies or integrating existing systems, it's essential to have a solid foundation. Organizations should develop a clear change strategy and a detailed roadmap before embarking on a digital transformation journey. A successful change management strategy will drive business readiness and user adoption from day one. With connected systems and effective change management, companies will increase effectiveness, eliminate gaps and inefficiencies, and ultimately speed trial execution and data delivery.

Advantages of Digital/Hybrid Trials

All respondents unanimously agree that enabling digital/hybrid trials is beneficial, citing increased trial efficiency (43%), improved site (34%), and patient experience (23%) as the top benefits.



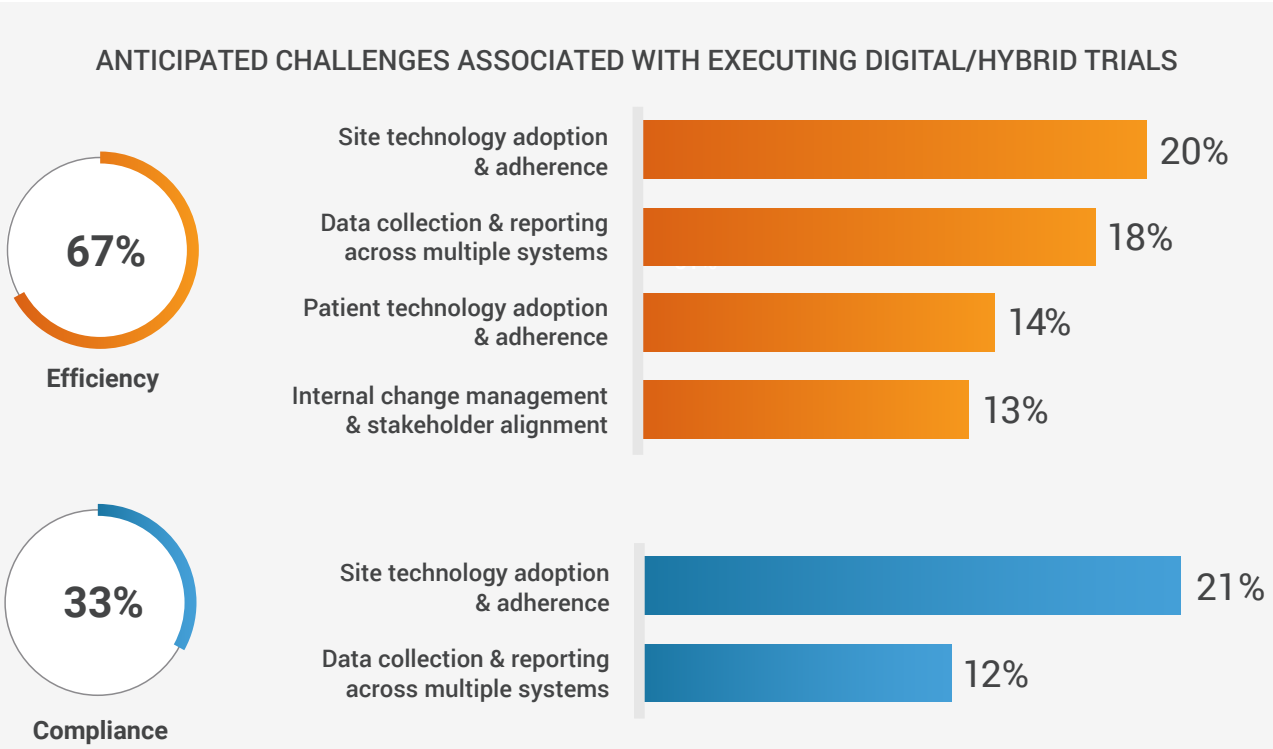
The industry is making strides toward bringing trials closer to patients and improving patient access and inclusion. A digital approach streamlines and simplifies patient-site interactions and vendor collaborations, enabling overall trial efficiency, and ensuring complete data integrity.

As medical device and diagnostic organizations shift to this model, it's imperative to have a clear strategy and scalable technology. The trial setting, design, and patient population are all crucial components to the strategy, as is stakeholder involvement and collaboration (i.e., vendors, CROs, sites, and patients).

A unified system connecting sponsors, sites, and patients can improve communication and collaboration. It will also enhance scalability and efficiency by reducing the technical debt of integrating disparate point solutions.

Anticipated Challenges with Digital/Hybrid Trials

Both device and diagnostic respondents anticipate efficiency (67%) and compliance (33%) as the main challenges when it comes to executing digital/hybrid trials.

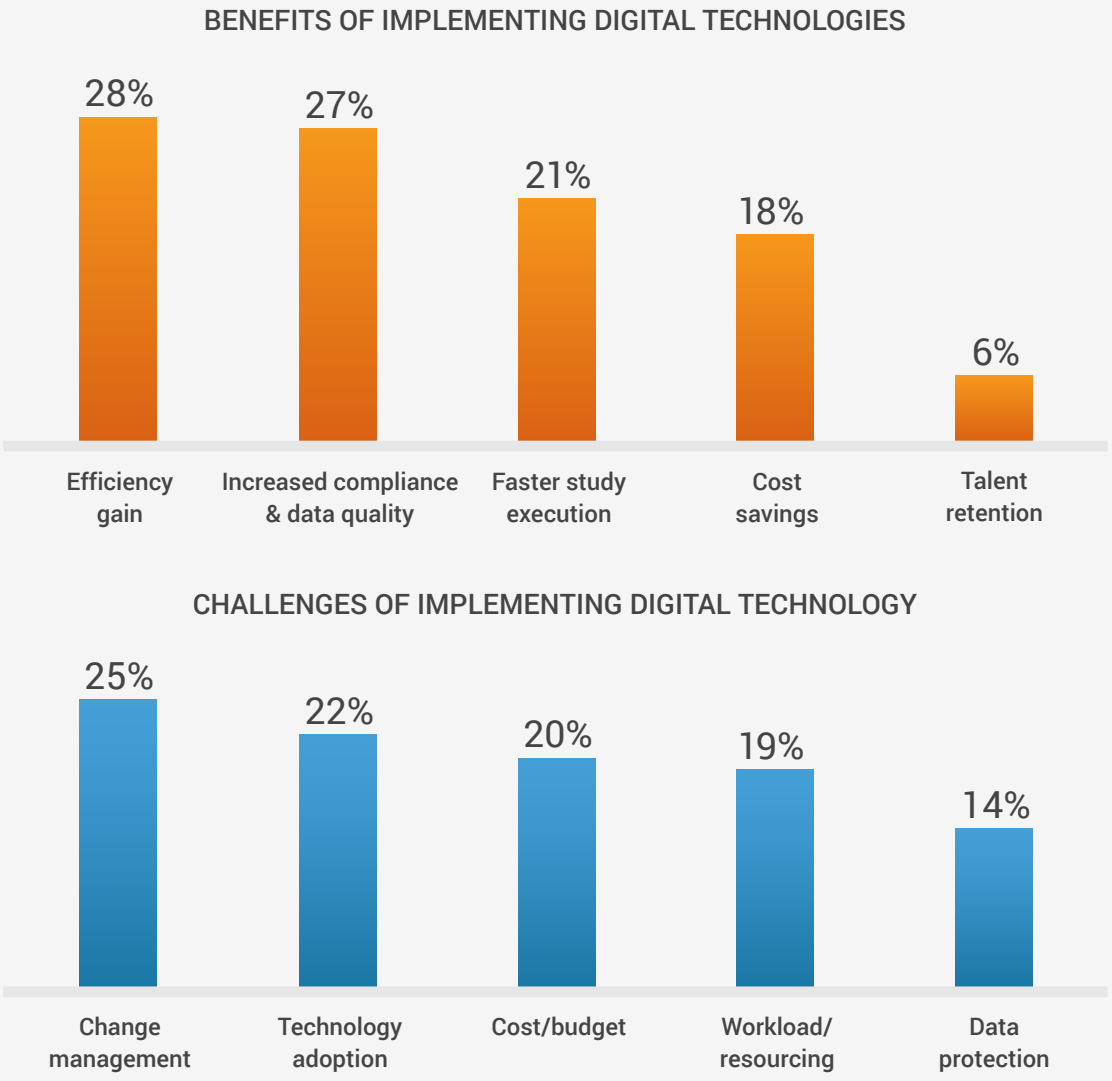


Across the globe, data privacy requirements are becoming more complex. Patients can request and manage clinical data under regulations like GDPR, giving them a greater say in data processing. Selecting a software that prioritizes data security and safeguards patient rights will allow organizations to stay ahead of local and global regulatory requirements.

Consider the entire clinical trial ecosystem when selecting a software partner and technology, taking all internal and external stakeholders' activities and data processing into account. With this approach, the system will address the key stakeholder needs and enable faster adoption to maximize process efficiency early on.

Anticipated Benefits & Challenges of Digital Technology

As the industry continues to move towards patient-centric trials, medtech organizations have an opportunity to reduce trial costs and streamline efforts by leveraging digital technologies. Medtech companies do anticipate benefits and challenges associated with going digital.



In recent years, medtech companies have had to scale processes and activities to deliver more clinical evidence and performance data in order to meet regulatory requirements (EU MDR and IVDR). Often, this meant proposing new technology that would help handle increased workloads.

However, managing change is not easy; it takes time and requires team buy-in. For any change to materialize, it must begin with a clear plan of action. It is estimated that 70% of change programs fail without a change management strategy. The most common pitfalls are framing

change as a challenge instead of an opportunity, expecting it to occur overnight, aiming for "big bang" change, and considering it a destination rather than a journey.

Before jumping into the journey and adopting new technology, there are a few upfront steps that should be taken to ensure success.

- Establish a governance structure that includes decision-making criteria, aligns operational models, and outlines an escalation path to help drive adoption and reinforce new ways of working.
- Define change management and business readiness strategies that include all internal and external stakeholders. Define a clear business case and vision and determine how much effort is required to achieve it.
- Analyze end-to-end business processes to identify inefficiencies and update procedures to reflect new working methods.
- Design and execute a multi-audience, two-way communication strategy to communicate value and understand sentiment and concerns of teams, which will get more buy-in and empower teams to enforce accountability and drive end-user adoption.
- Define KPIs for key clinical processes to track efficiency improvement over time and show the value of technology.

Conclusion

Medtech companies operate in a fast-paced, highly competitive environment, with limited resources (personnel and materials) and ever-increasing regulatory requirements. To remain competitive, grow businesses, and provide safe and effective devices and treatments to patients faster, organizations must increase operational efficiency.

A unified and connected trial ecosystem is crucial for device and diagnostic companies to conduct more efficient, compliant, and better-informed clinical studies, while improving patient experience and outcomes.

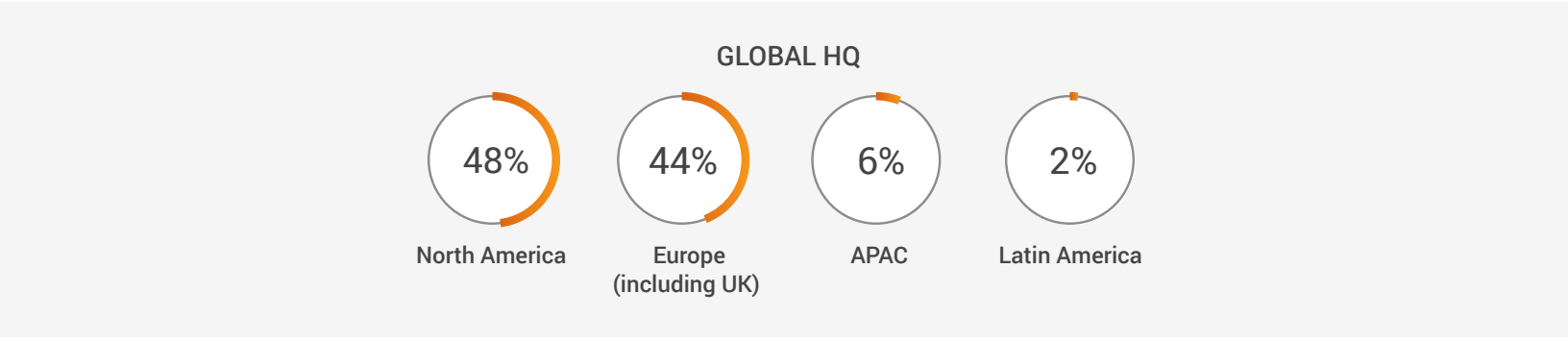
Learn how Veeva MedTech's Vault Clinical Suite enables organizations to unify clinical data and operations to get products to patients faster.

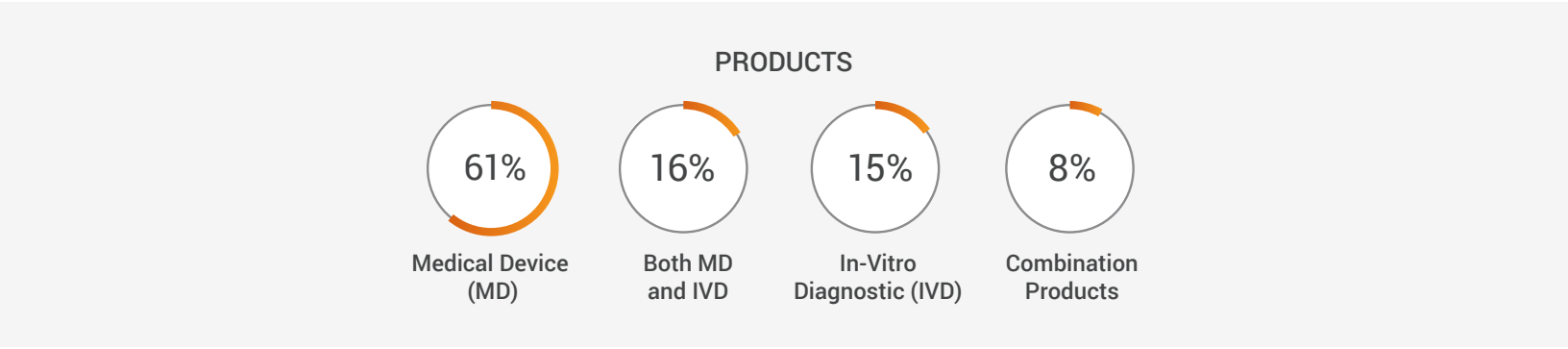
Survey Methods

The research comprised 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 partial or full responsibility for clinical trial or clinical development activities within their 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. All participants were offered a complimentary copy of a report upon the study's completion if indicated. No other compensation was offered or provided.

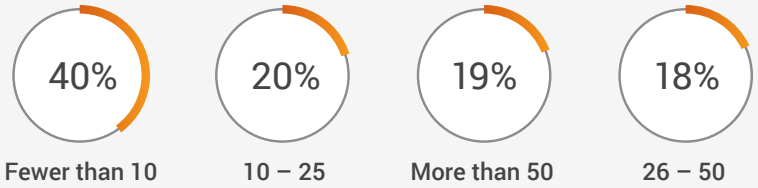
Survey Demographics

This survey includes responses from 135 qualified respondents with clinical roles in medical device or diagnostics companies.

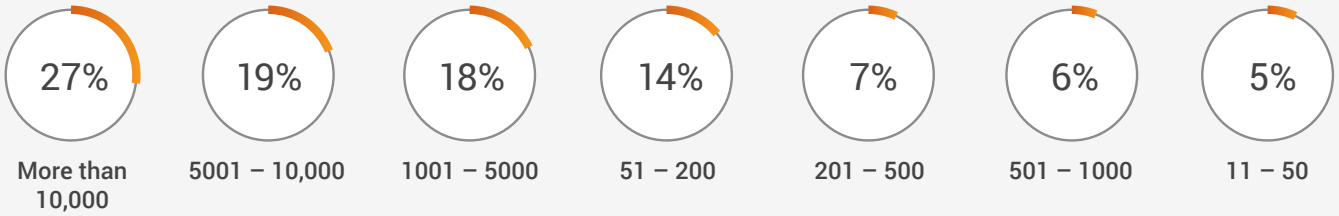




CLINICAL TRIALS PER YEAR



ORGANIZATION SIZE



CLINICAL DEPARTMENT SIZE