



MedTech Clinical Trial Readiness eBook

Up to 80% of Trials Stall. Here's How
Your Medical Device or IVD Trial Won't.



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Why MedTech Trials Fail & What Successful Sponsors Do Differently

Industry data reveal a hard truth: nearly 30% of MedTech trials fail to secure regulatory approval, while up to 80% experience costly delays or budget overruns.

What separates successful sponsors from failures? They follow a comprehensive and rigorous planning checklist from day one, covering everything from regulatory pathway optimization to operational efficiencies and risk management. Equally important, they partner with CROs who understand how to execute this specialized approach to make navigating through this difficult terrain easier.

Here's why this matters — MedTech trials operate in a completely different world than pharmaceutical studies. Instead of measuring biological responses, you're evaluating complex systems where success hinges on user competency, workflow integration, and technical performance benchmarks that don't exist in drug development. If you miss any of these specific requirements, setbacks become inevitable.

The companies that consistently succeed understand that a specialized CRO partner can help anticipate risks and proactively prepare and respond to any derailments, which can increase timelines and costs.

THE BEAUFORT DIFFERENCE

Beaufort's specialized MedTech expertise means we ensure planning is comprehensive and every element is executed with precision. Our teams have navigated the exact trial challenges your product will face, transforming potential obstacles into strategic advantages that position you for both regulatory and commercial success.

To help you better navigate MedTech trials, our experts developed the MedTech Clinical Trial Readiness eBook. Use its included checklist as a roadmap to assess your current readiness, identify gaps, and ensure every phrase of your trial is optimized from the start.

MedTech Clinical Trial **Readiness Checklist**

Successfully navigating a MedTech trial starts long before the first patient is enrolled. It begins with a strategic, end-to-end plan that accounts for the unique regulatory, operational, and technical demands of device development.

The following checklist outlines the essential components every sponsor should address to reduce delays, avoid costly missteps, and accelerate time to market.

- ☐ Develop a regulatory strategy
- ☐ Establish trial design and endpoint selection
- ☐ Identify intended use population and site selection
- ☐ Prioritize operational feasibility and execution
- ☐ Implement data collection, monitoring, review and analysis
- ☐ Incorporate risk management and quality assurance
- ☐ Consider commercialization and market access

Let's get started.

Develop a Regulatory Strategy

A sound regulatory strategy drives the success of the MedTech clinical trial program. Early engagement with regulatory authorities clarifies requirements and expectations, which directly informs the scope, duration, and endpoints of clinical trials. Furthermore, the regulatory roadmap will shape your entire global commercialization strategy.

To build a regulatory strategy that supports both near-term approvals and long-term commercial success, sponsors should address the following foundational questions early in the planning process:



Have you identified the correct regulatory pathway (e.g., FDA 510(k), De Novo, PMA, CE Mark, IVDR, MDR)?

Selecting the optimal regulatory pathway—whether 510(k), De Novo, PMA, CE Mark, IVDR, or MDR—is critical to planning your entire development strategy, evidence requirements, and timeline. Taking a fragmented approach or selecting an inappropriate pathway doesn't merely risk rejection; it can lead to prolonged or additional studies.

For IVDs especially, performance claims established early become the foundation of your validation strategy and cannot be easily modified later without substantial rework. A strategically designed global regulatory approach from the outset can significantly decrease development costs while maximizing your product's speed to commercialization and potential across all target markets.



Do you have clarity on the clinical utility rationale and supporting evidence for approval?

Developing a robust clinical utility rationale supported by compelling evidence is critical for regulatory success, particularly for IVDs where demonstrating real-world clinical impact directly influences approval decisions. Understanding precisely what evidence regulators expect ensures you collect the right data from the start, preventing costly redesigns or supplemental studies.

Investing in comprehensive clinical utility planning with regulatory expertise streamlines your path to approval while establishing the value proposition essential for both regulatory clearance and commercial success.



Have you engaged with regulatory authorities (e.g., pre-submission meetings with FDA, notified body consultations)?

Leveraging resources like the FDA's pre-submission process, and for IVD products, review of the FDA Decision Summaries, can clarify performance expectations and help align your trial with current regulatory requirements. These interactions provide invaluable feedback that can prevent delays due to product changes and protocol amendments during clinical trials. Without prior consultations with the appropriate regulatory agencies, clinical study costs and resources for both the site and the sponsor can increase significantly.



Have you considered post-market surveillance requirements for your medical device?

Today's regulatory frameworks demand a comprehensive product lifecycle approach, with post-market surveillance and clinical follow-up requirements becoming increasingly important. Early integration of post-market requirements into your development strategy ensures your initial clinical trials generate data that supports not only clearance/approval but also establishes the baseline for mandatory post-market studies, real-world performance monitoring, and periodic safety update reports.



Establish Trial Design & Endpoint Selection

A robust protocol with clear endpoints and data variables in support of the endpoints (and for IVD products, acceptance criteria) is essential to a successful clinical trial. Not only does a concisely written protocol align investigators and site staff, sponsors, and other stakeholders on their roles and responsibilities, it also ensures consistency in execution.

To ensure your trial generates the right data for both regulatory approval and market success, carefully consider the following questions during the trial design and endpoint planning process:



Have you determined the appropriate trial type (e.g., pilot/feasibility, pivotal, validation, post-market)?

Strategic selection of the appropriate trial type (e.g., pilot/feasibility, pivotal, post-market, and for IVD products, analytical and validation protocols) directly impacts your entire product development pathway and commercial success. Each trial type must be carefully sequenced to build a compelling evidence narrative that satisfies your specific regulatory requirements while maximizing commercial positioning, with IVD products requiring precisely designed analytical and clinical validation protocols to support performance claims. Companies that misalign trial types with their overall strategic objectives often face regulatory struggles, including limited claims that undermine commercial potential, even when their technology is fundamentally sound.



Are your endpoints aligned with regulatory expectations (e.g., clinical outcomes, usability, performance metrics) for both safety and effectiveness?

Endpoints must satisfy both regulatory requirements and clinical relevance. Misaligned endpoints risk collecting data that won't support your claims or address regulatory concerns, potentially requiring additional studies. FDA evaluates the overall benefit and value of a product, especially for diagnostic tests. The FDA focuses on ensuring that a product's benefits outweigh its risks, and clinical utility is often a factor in this assessment. Clinical utility is required by the Centers for Medicare and Medicaid Services (CMS) and other payers for coverage and reimbursement decisions and impacts provider adoption.



Have you accounted for human factors testing and real-world evidence needs?

Comprehensive human factors testing is essential for regulatory approval, as inadequate usability can result in costly redesigns. Real-world evidence (RWE) also has become central to regulatory decision-making across FDA and EU frameworks, providing crucial insights into device performance across diverse populations while supporting both approval and reimbursement strategies. Companies that integrate human factors and RWE planning early secure faster approvals and stronger market positioning, while those addressing these as afterthoughts typically face significant delays and competitive disadvantages.



Are you leveraging adaptive trial designs to increase flexibility?

Adaptive trial designs offer flexibility to modify aspects of the trial based on interim results, potentially saving time and resources while increasing the likelihood of a successful outcome in complex device studies. These flexible approaches are increasingly being accepted by regulatory agencies to accommodate the iterative nature of device innovation while maintaining scientific rigor. Companies implementing such strategies effectively gain competitive advantages through faster market entry and more efficient use of limited resources, which are particularly valuable for emerging technologies where initial assumptions about performance or patient response may evolve during the study lifecycle.



Identify Intended Use Population & Site Selection

Identifying the subject population consistent with your intended use population and clinical sites that enroll those subjects directly impacts enrollment success, data quality, and overall trial efficiency. Use of Artificial Intelligence (AI) to identify sites within a site database that fit the study criteria can further streamline site selection and accelerate the feasibility process.

Because insufficient planning in areas such as site identification and subject recruitment can drive delays or cost overruns, a thoughtful clinical site selection and enrollment strategy and plan are critical to a trial's success.

Selecting the right patient population and high-performing clinical sites is foundational to trial success. Use the following questions to evaluate whether your strategy will support efficient recruitment, high-quality data, and regulatory-grade outcomes from the start:



Have you identified accurate and current inclusion/exclusion criteria?

Properly defined inclusion/exclusion criteria ensure your device is tested in the population that will benefit most. Overly restrictive criteria frequently derail otherwise promising studies through recruitment challenges, while excessively broad criteria risk masking effects below statistical significance thresholds. For IVD developers specifically, inclusion criteria must carefully balance analytical performance across relevant demographic subgroups with sufficient enrichment of target conditions to demonstrate clinical utility, requiring specialized expertise in diagnostic trial design that general CROs typically lack. Companies that optimize their inclusion/exclusion criteria through strategic modeling of statistical power, recruitment feasibility, and regulatory expectations position themselves for faster clearance/approvals.



Are there sufficient eligible patients for recruitment?

Accurately forecasting the true availability of eligible subjects is perhaps the most frequently underestimated aspect of medical device trial planning. Overly optimistic recruitment projections that fail to account for subjects enrolling in competing trials, site-specific patient flow limitations, and other factors can extend timelines and increase costs substantially. Utilizing sophisticated pre-study feasibility assessments that incorporate historic screening data, detailed chart reviews at representative sites, and competitive trial landscapes can provide a data-based foundation for realistic recruitment targets.



Do you have access to sites with experience in MedTech trials?

Sites with established experience in MedTech, such as IVD, product trials possess the specialized expertise to manage both the complex subject pathway (including precise inclusion criteria, timing requirements, and reference standard procedures) and the equally critical sample pathway (encompassing collection, handling, processing, storage, and chain of custody documentation) that directly impact analytical and clinical validity results. This dual-pathway expertise becomes especially crucial for trials involving time-sensitive biomarkers, specialized collection techniques, or complex aliquoting protocols where even minor deviations can compromise sample integrity and potentially invalidate results. Experienced sites demonstrate significantly lower protocol deviation rates and hence deliver more reliable evidence for regulatory submissions.



Are you considering decentralized or hybrid trial elements to expand access?

Decentralized or hybrid trial designs can be accelerators for medical device and IVD studies. Techniques including eConsent platforms, home-based sample collection, telehealth visits, and direct-to-patient investigational product shipping can not only expand access to diverse populations but also dramatically improve retention rates by reducing participant burden. Forward-thinking sponsors are strategically selecting study elements to decentralize based on risk-benefit analysis, resulting in optimized protocols that maximize both enrollment efficiency and data integrity.

Prioritize Operational Feasibility & Execution

Medical device and diagnostic trials present unique operational challenges that demand specialized planning. These include, but are not limited to, proper device handling, complex procedures, and even supply logistics. Companies that prioritize operational planning and excellence will execute more seamlessly and consistently achieve faster enrollment rates, substantially fewer protocol deviations, and higher-quality data that strengthens regulatory submissions.

To ensure smooth execution and high-quality outcomes, sponsors must proactively address the unique operational demands of device and diagnostic trials. Use the questions below to evaluate whether your operational plan supports consistency, compliance, and efficiency across all trial activities:



Have you paid for site training?

An extensive review with site personnel on the specific requirements for handling devices, collecting data, or processing specimens is foundational to protocol compliance and data integrity in clinical trials. Having a dedicated Learning Management System (LMS) can transform this critical function by delivering standardized, trackable training modules with automated competency assessments that not only reduce site initiation timelines but also create comprehensive training documentation needed by regulators. Using this approach ensures consistent protocol application across all sites while dramatically reducing the administrative burden of training documentation.



Have you planned for supplies and samples handling requirements?

Medical devices require accessories to be included in the accountability, while IVDs include kits, reagents, and specific equipment used. Proper device handling planning is essential for medical device trials, as inconsistent handling protocols directly impact both patient safety and data integrity.

A comprehensive device handling plan must address the entire product lifecycle within the trial, including shipping logistics, calibration requirements, proper storage conditions, usage training, troubleshooting protocols, and end-of-study disposition procedures. This meticulous planning prevents data variability and supports a documented chain of custody, which regulators expect during their submission review.



Do you have strategies to minimize protocol deviations due to device complexity?

Device complexity significantly increases protocol deviation risk. Implementing a comprehensive Protocol Deviation Management Plan, integrated directly into your Data Management Plan (DMP), creates a systematic framework for deviation prevention, real-time identification, proper documentation, and timely corrective actions that preserve data integrity. This proactive approach helps continuously improve protocol design, site training, and operational efficiency throughout the study lifecycle.



Are you prepared for unique monitoring needs, including remote data collection?

Medical device and IVD trials demand fundamentally different monitoring approaches, with device studies requiring verification of proper usage techniques and training consistency, while IVD trials necessitate meticulous oversight of sample handling, processing workflows, and reference standard applications. Implementing technology-based monitoring solutions for these specialized needs drives operational efficiencies and avoids potential issues in trials.

Risk-Based Monitoring (RBM) strategies, particularly when incorporating remote data collection capabilities, enable targeted oversight of these product-specific critical processes while efficiently deploying resources to the highest-risk areas.



Implement Data Collection, Monitoring, Review & Analysis

Precise data collection and rigorous monitoring and analysis form the cornerstone of clinical trial success, directly determining whether your device receives regulatory approval or faces rejection. Advanced AI-powered data management systems are transforming this critical function by automating anomaly detection, accelerating data cleaning, and enabling real-time quality monitoring that identifies potential issues before they compromise study integrity.

For IVD products specifically, data collection demands unique considerations including specimen tracking, reference method comparisons, and analytical performance variables across diverse testing conditions. Companies that implement comprehensive data management strategies from protocol development through submission consistently generate higher-quality evidence with fewer queries, resulting in higher rates of regulatory clearance and approval.

High-quality evidence starts with a clear, purpose-built data strategy. Use the questions below to assess whether your data collection, monitoring, and analysis approach is designed to support both regulatory success and downstream commercialization:



Do you have a clear Data Management Plan?

A comprehensive Data Management Plan (DMP) serves as the foundation of regulatory success, establishing not only how endpoints will be collected but how they will be analyzed. These are critical factors which directly determine whether your clinical results will be accepted or rejected. For medical device and diagnostic trials, where specialized endpoints and unique analysis requirements are common, companies that invest in a rigorous and clearly defined DMP before study initiation consistently generate higher-quality evidence packages with fewer queries, ultimately producing compelling submissions that face significantly fewer regulatory challenges.



Are you leveraging digital tools for real-time data capture and remote data review?

Advanced digital tools for real-time data capture and remote review should be considered as they can vastly improve clinical trial efficiency by identifying and resolving data issues immediately. The use of advanced technologies like AI, machine learning, and automation is becoming increasingly embedded in the clinical trial management process and providing unprecedented visibility into trial progress. The real-time information that is gained enables data-driven decisions that can address emerging issues and accelerate timelines based on actual performance rather than delayed reports.



Have you planned for data monitoring and review?

Data monitoring and review are critical components of clinical trials that ensure the integrity of research findings. Continuous monitoring allows researchers to identify protocol deviations and data quality issues in real-time, enabling prompt corrective actions. Regular review of accumulating data helps determine whether a trial should continue, be modified, or be terminated early based on efficacy or safety signals. This systematic oversight not only meets regulatory requirements but also builds confidence in the trial's outcomes.



Is your trial designed to generate the level of evidence required for reimbursement strategies?

Regulatory approval and commercial success represent two entirely different evidence thresholds, with payers demanding robust economic and outcomes data that FDA and other regulatory bodies don't require. This difference in requirement can impact market adoption despite technical and clinical merit. Companies that strategically design trials to simultaneously satisfy both regulatory and payer requirements generate compelling value propositions and accelerate coverage decisions by avoiding additional studies.



Is your data capture system set up for device-specific metrics and integration?

A purpose-built data capture system designed specifically for your medical technology creates seamless integration between device outputs, clinical outcomes, and patient-reported experiences. Unique device-specific metrics, such as usability parameters, technical performance variables, and device-user interaction data, all impact safety and effectiveness determinations. Companies implementing these specialized data capture solutions achieve faster approval timelines and overall stronger submissions.



Has a Statistical Analysis Plan been established?

Establishing a Statistical Analysis Plan (SAP) before data collection and analysis is crucial for maintaining scientific rigor and avoiding bias in research studies. A pre-specified SAP ensures that conclusions are based on sound methodology rather than post-hoc decisions that could inflate the risk of false discoveries. Additionally, regulatory agencies and journal editors increasingly require evidence of pre-planned analyses to evaluate the validity and reliability of study findings.

Incorporate Risk Management & Quality Assurance

The underlying foundation to clinical excellence is having a proactive, systematic approach to risk management. Incorporating such a risk management strategy and developing contingency plans are crucial for preventing disruptions and ensuring compliance, as well as managing costs and timelines effectively.

Risk isn't a matter of if — it's a matter of when. The questions below will help you assess whether your trial is equipped with the proactive risk and quality safeguards necessary to stay compliant, minimize disruptions, and maintain data integrity from start to finish.



Do you have a robust risk management plan in place?

Identifying and addressing potential issues before they occur and in real-time keeps trials on track and within budget. With over 20 years of experience designing and managing clinical trials, Beaufort understands where challenges lie and how best to avoid and/or resolve them. Following the ICH E6(R3) "Good Clinical Practice" Guideline, we take a systematic approach using risk-based quality measures across sites, data, and operations to continuously monitor and reduce protocol deviations. This approach ensures regulatory compliance while enhancing data integrity and significantly reducing potential remediation costs that may arise otherwise.



Are you prepared for device-related adverse events and reporting requirements?

Proper preparation for device-related adverse events is essential for regulatory compliance, with inadequate systems often triggering FDA warning letters or clinical holds. Device studies face particularly stringent requirements that demand specific systems and trained personnel established before the first participant enrollment. Beyond regulatory obligations, comprehensive adverse event management protects participant safety while simultaneously generating the safety profile documentation critical for approval submissions and future marketing claims.



Does your trial comply with all applicable requirements, including the ICH E6(R3) Good Clinical Practice (GCP) guideline and ISO 14155 standards?

Adherence to ICH E6(R3) Good Clinical Practice guidelines and ISO 14155 standards ensures your trial data will be accepted by regulatory authorities worldwide. For medical device studies specifically, these frameworks provide the specialized structure needed to address unique device considerations, including proper handling, training requirements, and risk management procedures. Best practices in clinical trials include the implementation of these standards from protocol development through study close-out to consistently generate higher-quality data with fewer queries, leading to higher rates of approvals and clearance.

7 Consider Commercialization & Market Access

Regulatory approval, while essential, is not a guarantee of commercial success. Companies that fail to integrate commercialization and market access considerations into their clinical strategy will face significant challenges over the product lifecycle. Embedding these considerations into your protocol from inception rather than addressing them reactively, you will maximize your device's commercial potential.

These questions ensure your clinical strategy also builds a strong foundation for payer acceptance, reimbursement, and long-term market success by embedding commercialization and market access considerations early in the process



Are you generating data that supports payer and reimbursement discussions?

Generating evidence that demonstrates both clinical utility and economic value to payers is essential for commercial success. Companies need to integrate payer evidence requirements, including comparative effectiveness, budget impact analyses, and quality-of-life metrics, directly into their clinical trial design from inception, rather than as an afterthought. In an increasingly cost-conscious healthcare environment, this strategic approach not only accelerates revenue generation by substantially reducing the gap between approval and reimbursement coverage, but also significantly enhances market adoption and penetration.



Are you incorporating health economics and real-world evidence consideration?

Incorporating health economic endpoints and real-world evidence considerations into your clinical strategy matters for justification for pricing and coverage decisions. Studies that capture economic metrics such as resource utilization and hospitalization reduction, and real world evidence often lead to favorable reimbursement determinations and accelerated payer adoption.



Do you have a plan for post-market studies and regulatory commitments?

With regulatory bodies worldwide having dramatically expanded post-approval study requirements, proactive planning for these commitments during initial trial design can establish appropriate baseline measurements and create seamless continuity between pre- and post-market evidence generation. Companies that fail to set the foundation for efficient post-market research may face expensive remediation, including unplanned additional studies, or even temporary market removal when real-world performance doesn't align with approval-stage claims.

Accelerate Your Innovation with a **CRO That Gets MedTech**

MedTech clinical trials present unique challenges that require specialized expertise. At Beaufort, we are a full-service CRO for MedTech. Our extensive experience guides sponsors through the complexities of trial planning and enables precise, agile solutions, helping to accelerate your innovations to market. We can meet you where you need us.

Ready to start your MedTech journey with us?

Connect with our experts today to discuss your specific needs and learn how we can support you.

