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FROM CONCEPT TO MARKET

**HOW EARLY-STAGE MEDICAL
STARTUPS CAN LEVERAGE
FRACTIONAL CRO MODELS FOR
SUCCESS**

1. INTRODUCTION

1.1 THE JOURNEY FROM CONCEPT TO MARKET: AN OVERVIEW

Bringing a medical device from concept to market is a multi-phase process that involves several critical stages: discovery, preclinical research, clinical trials, regulatory approval, and market entry. For early-stage medical startups, however, this journey is fraught with challenges, including limited resources, tight timelines, and the need for precise, scientifically rigorous data.

According to industry data, 75% of medical device startups fail before reaching the market. The reasons for this high failure rate include underestimating regulatory complexity, mismanaging clinical trials, and lacking the right strategic partnerships. Founders must be highly vigilant in securing specialized expertise to navigate these critical stages successfully.

The typical stages of development include:

- **Discovery and Ideation:** Early research and validation of the product concept.
- **Preclinical Research:** Testing prototypes, conducting feasibility studies, and gathering early-stage data.
- **Clinical Trials:** Conducting trials in phases to gather data on the product's safety and efficacy.
- **Regulatory Approval:** Submitting data and documentation to regulatory bodies such as the FDA or EMA for approval.
- **Market Entry:** Launching the product, supported by clinical evidence and regulatory clearance.

Each of these stages requires deep expertise in clinical research, regulatory compliance, and trial management—areas where many startups struggle due to limited funding or internal talent.

Support Data Source: <https://www.fusfoundation.org/posts/the-complex-ecosystem-of-a-medical-device-startup/>

1.2 THE RISE OF A NEW HYBRID MODEL: COMBINING CRO AND FRACTIONAL EXPERTS

In recent years, the clinical research landscape has evolved to better serve the needs of startups. While traditional **Contract Research Organizations (CROs)** have been indispensable for managing end-to-end clinical trials, startups are increasingly adopting **fractional expert models** that offer flexibility and cost-efficiency.

The hybrid approach combines the breadth of services provided by traditional CROs with the flexibility and scalability of fractional teams. This model allows startups to engage the right expertise at the right time while avoiding the high overhead associated with traditional CROs. In the following sections, we will delve into both traditional CROs and fractional clinical research teams, followed by an analysis of how the hybrid model optimizes outcomes for medical device startups.



2. THE CHALLENGES OF EARLY-STAGE MEDICAL STARTUPS

2.1 LIMITED RESOURCES AND EXPERTISE

For early-stage medical device startups, a lack of resources—both financial and human—is one of the most significant challenges. These startups often operate with small teams and limited funding, which makes it difficult to hire in-house clinical research experts or invest in costly long-term partnerships with CROs.

Data shows that **21.5% of startups fail in their first year**, with the failure rate increasing to **50% by the fifth year**. For medical device startups, these numbers are even higher, with approximately **75% of US-based medical device startups failing** before reaching market entry. One of the major contributing factors to this failure rate is the inability to conduct well-designed and properly funded clinical studies. Without the right clinical data, startups struggle to demonstrate the efficacy and safety of their products, a critical requirement for regulatory approval and market entry.

Medical device clinical trials present distinct challenges compared to pharmaceutical trials. Trial designs often need to accommodate device-specific factors, such as adjustments to device prototypes during the trial or specialized training required for clinicians and patients.

Additionally, medical devices frequently have diverse endpoints—such as usability or long-term functionality—that can be harder to measure consistently. Regulatory requirements also vary significantly across global regions, with evolving standards and data privacy regulations adding further complexity.

While device trials may be smaller in scale than many pharmaceutical trials, managing the timelines and costs effectively is critical. Long-term monitoring, the potential for modifications, and the need for specific expertise in device operations can create hurdles for startups. As trial designs have become more intricate across therapeutic areas, many startups struggle to maintain progress without sufficient funding and expert guidance, leading to stalled development and eventual failure.

2.2 NAVIGATING COMPLEX REGULATORY PATHWAYS

Regulatory approval is one of the most difficult challenges for medical device startups, especially when navigating agencies like the **FDA** or obtaining a **CE Mark** for European markets. The **FDA approval process** for medical devices can take anywhere from **3 to 7 years**, with over **77% of the cost** of bringing a product to market spent on regulatory and FDA-related activities.

Startups often underestimate the amount of clinical data required to support their regulatory submissions, leading to significant delays or outright denials. Regulatory issues are a major reason why 90% of digital health startups fail within their first five years, and similar challenges apply to medical device companies.

Furthermore, the lack of internal expertise in navigating these regulatory hurdles means that startups frequently face roadblocks in securing approvals. Without comprehensive clinical data, startups risk being unable to prove the safety and efficacy of their devices, which is essential for securing regulatory approval and gaining market access globally.

2.3 ACCELERATING TIME-TO-MARKET WITHOUT COMPROMISING QUALITY

For medical device startups, the pressure to get to market quickly is real. However, moving too fast without proper trial planning can lead to costly mistakes. One common challenge is designing clinical trials that clearly demonstrate how effective a device is, especially since medical devices require unique trial approaches that account for their specific functions and patient outcomes.



Startups must balance the need for speed with the necessity of conducting thorough, scientifically valid trials. Rushing through trials without sufficient planning can lead to trial failures, regulatory rejections, and the loss of potential investor confidence. These delays not only slow the path to market but also significantly increase costs, often leading to the collapse of the startup before the device reaches commercialization. By prioritizing strong trial designs from the outset, startups can ensure they collect the data needed to satisfy regulators and support marketing claims while maintaining investor confidence. It is about doing things right the first time, ensuring that speed doesn't come at the cost of quality and accuracy.

Support Data Source: <https://anatomisebiostats.com/biostatistics-blog/report-why-do-clinical-trials-fail/>



2.4 BALANCING COST AND EXPERTISE IN PARTNERING CHOICES

One of the most difficult decisions for medical device startups is choosing the right partner for clinical trials and regulatory support. Startups must decide between working with academic institutions, hiring internal teams, or engaging with **Contract Research Organizations (CROs)**. Each option comes with its pros and cons.

- **Academic institutions** offer specialized knowledge but are often slow-moving and lack the practical, regulatory experience needed for fast market entry.
- **Hiring internal teams** can be prohibitively expensive, especially given the complexity of the medical device approval process.
- **CROs** provide comprehensive services but are often costly and slow, requiring long-term contracts that many early-stage startups cannot afford.

This leads to one of the key reasons why 60% of health tech startups fail within the first five years—a lack of funding and poor allocation of resources for critical clinical studies. Startups often misjudge how much they need to allocate for clinical trials, regulatory submissions, and ongoing data collection, which further compounds the difficulties they face as they try to balance speed, cost, and regulatory requirements.

Support Data Source: <https://www.fusfoundation.org/posts/the-complex-ecosystem-of-a-medical-device-startup/>

3. UNDERSTANDING TRADITIONAL CROS, FRACTIONAL CLINICAL RESEARCH TEAMS, AND THE COMBINED APPROACH



3.1 WHAT IS A TRADITIONAL CRO?

A **Contract Research Organization (CRO)** is a full-service provider that manages the entire clinical trial process. From trial design and regulatory submissions to patient recruitment and data analysis, traditional CROs offer a one-stop solution for managing the complex and resource-intensive clinical trial process.

Pros of Traditional CROs:

- **Comprehensive Expertise:** CROs handle every aspect of the clinical trial lifecycle, offering deep expertise across various stages, including regulatory submissions, patient recruitment, trial management, and post-market surveillance.
- **Streamlined Processes:** Managing the entire trial process under one roof reduces miscommunication between teams, helping prevent delays and errors.
- **Regulatory Experience:** CROs have deep knowledge of regulatory frameworks like FDA's PMA and CE Mark processes, guiding startups through complex regulatory landscapes.

Cons of Traditional CROs:

- **Cost:** Traditional CROs can be prohibitively expensive for startups, often requiring long-term contracts with substantial upfront payments.
- **Lack of Flexibility:** Startups may find themselves locked into rigid, long-term contracts, limiting their ability to scale services based on changing needs.
- **Slow:** Traditional CROs are typically made up of large teams including administrative staff that may or may not have any experience in clinical research. These large teams are slow to change and build and may not have the specialized knowledge to streamline.

3.2 WHAT IS A FRACTIONAL CLINICAL RESEARCH TEAM?

A Fractional Clinical Research Team is a more flexible model that allows startups to access specialized clinical expertise on a part-time or project basis. These teams provide targeted support at specific stages of the clinical trial, enabling startups to avoid the costs associated with hiring traditional CROs.

Pros of Fractional Clinical Research Teams:

- **Cost Efficiency:** Startups only pay for the services they need, which makes this model far more cost-effective than traditional CROs.
- **Operational Flexibility:** These teams allow startups to scale services up or down based on the specific needs of the project. They are also more agile when changes occur to an ongoing project.
- **Targeted Expertise:** Fractional teams often consist of specialized experts in fields like regulatory strategy, patient recruitment, and data analysis. These experts design projects and studies customized for the startup and with reduced overhead and time to launch.

Cons of Fractional Clinical Research Teams:

- **Scaling Difficulty:** While fractional teams offer flexibility, they may lack the infrastructure to manage large-scale or highly complex trials.
- **Manage Multiple Vendors:** Startups may need to manage multiple providers for large studies, which can add complexity and time to project management.

3.3 THE COMBINED APPROACH: A NEW TYPE OF PARTNER FOR STARTUPS

The hybrid approach—combining the comprehensive services of a traditional CRO with the flexibility of fractional support—is an ideal solution for startups. This model allows startups to scale support as needed while maintaining access to the full range of CRO services.



Why this hybrid approach is ideal for startups:

- **Full-Service Capabilities with On-Demand Flexibility:** Startups can access the full range of CRO services—regulatory guidance, trial management, and data analysis—while scaling support based on their current needs.
- **Cost-Effective Scaling:** The hybrid model allows startups to pay only for the services they need, reducing costs while still accessing high-quality expertise.
- **Comprehensive Support with Tailored Solutions:** The combined model offers customized support, ensuring that startups have access to the right expertise at the right time while maintaining the benefits of a traditional CRO.

Supporting Data:

- **2023 ISR Reports:** Pharmaceutical companies using hybrid CRO models reduced clinical trial timelines by an average of 25% and achieved 20-35% cost savings across Phase I-III trials.
- **2022 Clinical Leader Study:** Biotech startups using hybrid FSP/FSO models saw a 28% faster time-to-market for lead candidates and reported 32% lower clinical development costs.
- **2023 Tufts Center for the Study of Drug Development:** Sponsors utilizing customized hybrid outsourcing reduced clinical trial cycle times by 22% and decreased development costs by 30% compared to traditional models.
- **2024 Frost & Sullivan Analysis:** Mid-size pharma companies adopting hybrid CRO partnerships reduced time-to-market by 18-24% and achieved 25-40% cost efficiencies across their R&D portfolios.

While these studies focused on pharmaceutical startups, the same benefits apply to medical device companies, as both industries require rigorous clinical trials, regulatory submissions, and careful resource allocation to bring products to market faster and more cost-effectively. Medical device startups typically have lower margins and lower budget for trials, making this model even more beneficial. **Founders of medical device startups should take note of this emerging trend and explore hybrid CRO models as a strategic solution** to reduce time-to-market, control costs, and ultimately accelerate their path to success

4. LEVERAGING FRACTIONAL CROS THROUGHOUT THE DEVELOPMENT LIFECYCLE

4.1 Early-Stage Research and Clinical Development

Fractional CROs can be engaged early to assist with critical aspects of research, feasibility studies, and protocol design. This targeted support helps startups define the scope of their clinical projects while ensuring alignment with regulatory requirements.



4.2 Clinical Trial Design and Management

Designing Robust Clinical Trials on a Startup Budget: Fractional CROs help startups design scientifically rigorous trials on limited budgets. These CROs offer expertise in structuring trials to optimize data collection while minimizing unnecessary expenses, and ensuring resources are used effectively.

Leveraging Fractional CROs for Effective Patient Recruitment and Retention: Patient recruitment is one of the most common challenges in clinical trials. Delays in recruitment can significantly extend time-to-market and unnecessarily increase costs due to the high expenses associated with patient recruitment efforts. With their specialized recruitment strategies, Fractional CROs can streamline this process, ensuring that startups efficiently reach their target sample size.

Effective retention strategies are also crucial for the success of a clinical trial. Patient dropout can add additional costs and unexpected delays. It can also impact the quality of data collected. Implementing customized retention plans that focus on continuous patient engagement throughout the study lifecycle reduces the risk of dropout, helping to keep the trial on track and within budget.

Managing Clinical Data: From Collection to Analysis: Data quality is a key factor in the success of clinical trials. Poor data integrity can lead to rejected regulatory submissions and delayed market entry. Fractional CROs provide expertise in clinical data management, ensuring accurate data collection and analysis, which supports compliance with regulatory standards and reduces the risk of trial delays.

4.3 Regulatory Strategy and Submissions

Developing a Regulatory Strategy with Fractional Support: Navigating regulatory requirements can be complex, particularly for startups entering international markets. Fractional CRO regulatory experts help develop a tailored regulatory strategy, ensuring that startups meet the stringent requirements of authorities like the FDA or EMA.

Preparing for Successful Regulatory Submissions and Approvals: Preparing regulatory submissions is a time-consuming process that requires precision. Mistakes in submissions can lead to delays or rejections, which are costly for startups. Fractional CROs provide expertise in preparing and submitting the necessary documentation, increasing the chances of a successful first-time submission.

5. BEST PRACTICES FOR WORKING WITH FRACTIONAL CROS

5.1 Identifying the Right Partner for Your Needs

Selecting the right fractional CRO is crucial for the success of any startup. The selection process should focus on:

- **Experience in Device Trials:** Ensure that the CRO has deep experience in the medical device sector, as clinical trial requirements can differ significantly from pharma.
- **Regulatory Knowledge:** A CRO with extensive knowledge of regulatory landscapes can help avoid common pitfalls during submissions, reducing time-to-market.
- **Technical Proficiency:** In today's environment, CROs must have expertise in digital tools like Electronic Data Capture (EDC) platforms and AI-driven analytics.
- **Operational Fit:** The best CRO partner will be one that fits culturally and operationally with the startup, promoting smooth communication and collaborative decision-making.

5.2 Establishing Clear Goals and Expectations

Successful collaborations begin with clear, measurable goals. This ensures alignment between the startup and the CRO, reducing the likelihood of miscommunication. Startups should:

- **Set Milestones:** Milestones should be defined for every phase of clinical development, such as the completion of protocol design or patient recruitment targets.
- **Define Success Metrics:** Mutual agreement on Key Performance Indicators (KPIs) is essential to measure progress, such as data quality metrics and adherence to regulatory timelines.
- **Maintain Agility:** Flexibility is key in clinical research, as unexpected challenges often arise. CROs should be able to pivot quickly in response to changes in trial protocols or recruitment.

5.3 Managing Communication and Collaboration

- **Regular Check-Ins:** Frequent meetings help ensure that the project remains on track. Depending on the complexity of the project, this may range from weekly stand-ups to monthly reviews.
- **Use of Collaboration Tools:** Leveraging digital collaboration tools like Smartsheet or Trello allows both internal teams and fractional partners to remain aligned. These tools offer transparency and real-time tracking of project progress.
- **Clear Accountability:** Defining ownership for each task or phase within the project ensures accountability and smooth project management.

5.4 Measuring Success and Adjusting Strategy

Regular assessment of performance metrics is critical to adjusting strategy as needed:

- **KPIs:** Key performance indicators should be tracked consistently, including project speed, data quality, and regulatory adherence.
- **Adjusting Strategy:** If performance metrics indicate that the trial is off track—such as delayed patient recruitment or errors in data collection—fractional teams can adjust focus to resolve these issues.



6. INTRODUCING ACTIVIE: A NEW GENERATION CRO

As medical device startups face increasing complexity in navigating clinical trials and regulatory pathways, the need for a flexible, comprehensive, and experienced partner has never been greater. ActiVie stands out as a new-generation CRO that offers both full-service support and a scalable, fractional model tailored to the needs of early-stage medical device companies.

6.1 ActiVie's Strategic Advantage: A Partner Built for Medical Device Startups

ActiVie offers medical device startups the **best of both worlds**—the comprehensive capabilities of a traditional CRO and the **flexibility of fractional teams**, making it an ideal partner at every stage of clinical research and development. Here's how ActiVie aligns with the essential qualities startups need in a partner:

- **Deep Understanding of Market Position and Study Design:** ActiVie's unique strength lies in its ability to align clinical trial design with each startup's specific business strategy. For early-stage companies with limited product offerings, it's crucial to run efficient trials that focus on collecting only the most necessary data. By understanding both the business and market position of each startup, ActiVie tailors trials to be fit-for-purpose, ensuring optimal use of resources without compromising on scientific rigor or regulatory compliance. This targeted approach minimizes complexity, accelerates timelines, reduces costs, and ultimately helps startups position themselves competitively in the market.
- **Experience in the Relevant Therapeutic Area:** With extensive experience working specifically with medical device companies, ActiVie understands the unique technical and clinical challenges that these startups face. From trial design intricacies to navigating the complexities of medical device regulations, ActiVie's in-depth knowledge helps startups overcome hurdles quickly, reducing learning curves and ensuring trials are designed and executed efficiently. This expertise positions ActiVie as a valuable partner in ensuring the clinical success of devices at all stages of development.

- **Regulatory Knowledge:** ActiVie’s team brings a wealth of experience in navigating the complex regulatory landscapes required for medical device approvals, including FDA, EMA, and other global authorities. By guiding startups through IDE applications, CE Mark approvals, and various regulatory processes, ActiVie ensures that all submissions are accurate and timely, reducing the risk of delays that could impact market entry. This deep regulatory expertise provides startups with the assurance that their path to commercialization remains smooth and on schedule.
- **Technical Proficiency:** Leveraging cutting-edge digital tools such as Electronic Data Capture (EDC), Clinical Trial Management System (CTMS), and electronic Trial Master File (eTMF) platforms and AI-driven trial optimization systems, ActiVie ensures the highest standards of data accuracy, real-time tracking, and efficient trial management. These technological capabilities empower startups to make informed, data-driven decisions throughout the clinical trial process, ensuring that studies are managed effectively and progress is closely monitored.
- **Cultural and Operational Fit:** ActiVie prides itself on fostering strong, collaborative relationships with its clients. The company takes the time to understand the specific needs of each startup, ensuring a cultural fit that promotes smooth communication and operational alignment. Whether it’s through regular check-ins or transparent use of project management tools, ActiVie operates as an extension of your team, not just a service provider.

6.2 ActiVie’s Founder Story: Building for Flexibility and Comprehensive Support

ActiVie was **founded by Jana Montgomery**, PhD, who has a decade of experience in the medical device and clinical research space. Jana recognized the unique challenges that medical device startups face in bringing innovative products to market—particularly the need for flexibility and comprehensive support.

Drawing on her extensive background, Jana created ActiVie to address these specific needs. Her vision was to develop a CRO model that allows startups to scale their engagement based on the evolving demands of their projects. This hybrid approach combines the comprehensive services of a traditional CRO with the scalability of fractional teams, giving startups access to a partner that grows with them.

Jana’s leadership and experience have been pivotal in shaping ActiVie’s success. Under her guidance, ActiVie has helped medical device startups navigate complex regulatory pathways, streamline clinical trials, and accelerate time-to-market. At the core of her approach is her human-first philosophy, which emphasizes the importance of prioritizing people—whether it’s patients, clinical trial participants, or her own team—throughout the clinical research process. This philosophy influences every decision at ActiVie, from designing patient-centered clinical trials to fostering meaningful, transparent relationships with clients.

Jana's commitment to providing both flexibility and high-quality service has made ActiVie a trusted partner for startups looking to bring life-changing technologies to market efficiently and effectively. By centering her human-first approach, Jana ensures that ActiVie remains focused not only on clinical and regulatory success but also on the well-being and ethical considerations of everyone involved in the journey.

6.3 Why ActiVie is the Ideal Strategic Partner

By combining the full-service offerings of a traditional CRO with the adaptability of fractional teams, ActiVie is uniquely positioned to support startups at every critical stage of clinical development. For medical device startups, where time-to-market is crucial and regulatory hurdles are significant, ActiVie provides the expertise, flexibility, and operational excellence required to bring innovative products to market faster, more efficiently, and with greater regulatory compliance.

ActiVie's success with medical device startups is rooted in its ability to offer:

- **Scalable, flexible services** that adjust to the startup's evolving needs.
- **Cost-effective solutions** that allow startups to optimize resources without sacrificing quality.
- **Comprehensive regulatory expertise** that ensures startups meet submission standards and timelines.
- **Advanced technological capabilities** that streamline data management and enhance trial performance.

By partnering with ActiVie, startups gain a strategic ally that understands the specific challenges of medical device development and is committed to their success.

7. CASE STUDY: SUCCESS STORY OF A STARTUP USING FRACTIONAL CROS

Key Summary:

A pioneering medical device startup was facing critical challenges in managing its clinical trial data due to a contract research organization (CRO) with insufficient experience. These challenges threatened the integrity and success of their ongoing trial. ActiVie stepped in with a transformative solution—modernizing the startup’s trial and data management infrastructure and deploying advanced data visualization tools. The result was a dramatic improvement in trial oversight, compliance, data accuracy, operational efficiency, and site satisfaction.

Challenge:

The startup’s original CRO was creating a series of cascading issues:

- **Inconsistent Data Quality:** Frequent data errors and lack of data management jeopardized the reliability of trial outcomes.
- **Poor Communication:** Poor communication while managing a global first-in-human trial resulted in confusion, missed items, redundancy, and risk to regulatory compliance.
- **Limited Data Insights:** The existing system offered limited reporting capabilities across disjointed systems, hindering the team’s ability to make data-driven decisions in real-time.
- **Risk of Non-compliance:** The original CRO did not have sufficient operations procedures resulting in gaps in the trial master file and delayed safety reporting.

These issues posed a significant risk to the trial's success and threatened to delay crucial regulatory submissions.

ActiVie's Solution:

Recognizing the urgency and limited resources, ActiVie executed a comprehensive overhaul of the startup's trial management and operations:

- **Trial Systems Upgrade:** ActiVie replaced the cumbersome systems with compliant, cost-effective, and collaborative ones. This upgrade significantly improved trial oversight capabilities and data accuracy.
- **Comprehensive Procedures:** ActiVie created an entire suite of clinical trial-specific procedures and templates for the Sponsor to manage their trials.
- **Compliant CRFs:** Tailored case report forms (CRF) were developed per the protocol and mapped to existing data for import, ensuring high data integrity and reduced site burden.
- **Advanced Data Management:** To empower the startup's team, ActiVie introduced advanced data management procedures and visualization capabilities, allowing for real-time tracking of trial progress and actionable insights.

Results:

ActiVie's solution delivered measurable improvements that had an immediate and lasting impact on the startup's clinical trial operations:

- **Significant Reduction in Data Errors:** The new EDC platform drastically reduced data inaccuracies, ensuring reliable trial results and a smoother path to regulatory submissions.
- **Increase in Operational Efficiency:** The automation and optimization of trial management processes accelerated trial timelines, enabling the startup's team to focus on higher-value activities.
- **Enhanced Data-Driven Decision Making:** The advanced data visualization tools allowed the team to monitor trial performance in real-time, identifying bottlenecks and making informed adjustments that kept the trial on track.
- **Cost Savings:** By streamlining trial management processes and minimizing errors, the startup realized significant cost savings, enabling them to reinvest resources into other critical areas of their clinical development.

ActiVie's comprehensive solution did more than just resolve immediate issues with the startup's clinical trial management. By deploying **state-of-the-art trial systems** and **advanced visualization tools**, ActiVie enabled the startup to elevate its entire clinical trial operation. The reduction in data errors, combined with increased efficiency and enhanced real-time decision-making capabilities, resulted in a streamlined trial process that saved time and mitigated the risk of costly regulatory delays.

Moreover, the startup's leadership recognized the strategic value of these improvements beyond just the current trial. With their data infrastructure optimized and scalable, they are now equipped to handle future trials more effectively, ensuring faster paths to regulatory approval and market entry. The cost savings from improved operational efficiency can now be reinvested into further innovation, fueling their growth as a leader in medical device technology.

ActiVie's intervention proved to be a pivotal moment for the startup, reinforcing the importance of partnering with a flexible, forward-thinking CRO capable of delivering both short-term wins and long-term advantages. By choosing the right strategic partner, the startup has not only strengthened its current trial outcomes but has also set the stage for continued success in a highly competitive and regulated market.

Note: The name of the startup featured in this case study has been withheld due to their ongoing efforts to raise funding for future trials. We respect the confidentiality of our clients and have anonymized their information to protect their business interests.

8. CONCLUSION

8.1 The Future of Clinical Research for Medical Startups

The future of clinical research for medical startups is increasingly shaped by the need for flexibility, scalability, and cost efficiency. As competition grows and regulatory demands evolve, startups must adapt to survive. Fractional CRO models will be central to this evolution, offering startups access to critical expertise without the long-term financial commitments or overhead of traditional CROs.

With **75% of medical device startups failing before reaching market**, due to factors like **regulatory unpreparedness** and **poorly managed clinical trials**, choosing the right strategic partner is vital. Fractional CROs offer the flexibility to scale as needed, helping startups meet regulatory milestones and manage resources efficiently.

Looking ahead, advancements in digital tools, data analytics, and AI will further enhance the capabilities of fractional CROs. Startups will increasingly seek partners who can integrate these technologies into trial design, patient recruitment, and data management, ensuring they remain competitive in a rapidly evolving landscape.

Support Data Source: <https://www.fusfoundation.org/posts/the-complex-ecosystem-of-a-medical-device-startup/>

8.2 Why Fractional CROs Are a Game-Changer for Startups

For early-stage medical device startups, fractional CROs offer a strategic advantage by providing specialized expertise on demand, helping startups navigate regulatory pathways and manage limited resources without sacrificing quality or speed. This model enables startups to tap into critical resources exactly when needed, reducing overhead costs and allowing for greater agility in adjusting strategies based on new data or regulatory feedback.

The cost savings of a fractional model are substantial. Startups can avoid long-term contracts and instead pay for services on a project-by-project basis, ensuring every dollar is directed toward activities that directly support market entry. This is especially valuable for startups with limited capital, where financial efficiency is key.

When speed is critical and every decision matters, fractional CROs like ActiVie offer the right mix of **scalability** and **flexibility**. Startups can reduce delays, improve data integrity, and meet regulatory demands without the heavy financial burden of traditional models. ActiVie's hybrid approach combines full-service capabilities with the agility of fractional support, positioning startups for success as they move from concept to market.





9. CALL TO ACTION

Ready to accelerate your journey from concept to market? Partner with ActiVie's expert fractional CRO model to streamline your development process, reduce costs, and achieve your goals faster. Visit activieresearch.com or book a complimentary consultation with ActiVie founder

Jana Montgomery by scanning the QR code below to learn how we can support your success.

