RQM+
Evolving MedTech

Answering the Tough Questions:

What Innovators Really Want to Know About Partnering With a Specialized MedTech CRO

The standard CRO model is no longer working for MedTech innovators in an era of constantly shifting regulations and rising clinical complexity. We provide you with direct, transparent answers to the hardest questions executives ask when evaluating a specialized MedTech CRO.

The Strategic Reality of MedTech Partnership

Question 1: We've been burned by our CRO before. How do we know this will be different?

The Answer: The most common frustration we hear is lack of ownership. Sponsors feel like they're managing their CRO instead of being supported by one. They describe missed timelines, poor communication, unexpected budget changes, and teams that don't really understand MedTech.

The Proof: RQM+ teams understand MedTech, regulatory pathways, and device-specific risks because that's all we do. That means fewer missteps, faster decisions, and a proactive approach, rather than constant course correction. Our long-term clients tell us we feel like an extension of their own team, not a vendor they have to supervise.

Question 2: How do we know you'll actually hit timelines and manage risk?

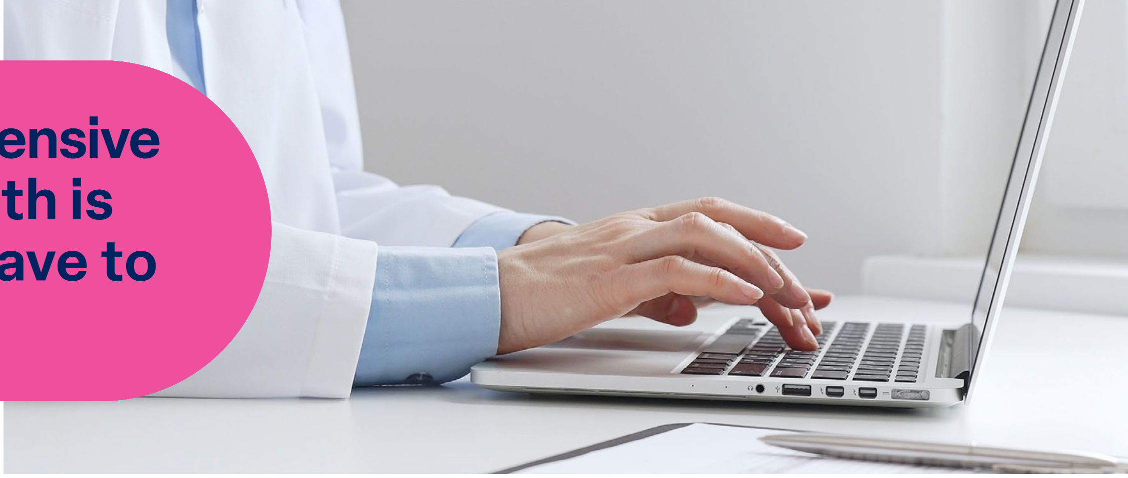
The Answer: The biggest differentiator is that we align clinical execution with regulatory expectations upfront. That's what prevents delays to your progress. It requires strategic alignment from the start and project management discipline throughout.

The Proof: We operate with structured project governance, clear communication, and proactive risk identification. We've stepped into programs where endpoints weren't aligned with regulatory expectations and adjusted the strategy without requiring a full study rebuild. That's how we help you avoid the "redo trap."

Question 3: Aren't you too specialized to handle our full program?

The Answer: A common misconception is that specialized CROs are limited in scale. For RQM+, specialization is the foundation of our SMART Solutions partnership model, which is designed to provide you with the operational capabilities of a global powerhouse combined with the technical focus of a boutique MedTech CRO. Whether you need deep support in one functional area or a fully integrated life cycle partner, we give you the infrastructure to manage your entire program from concept to post-market without the friction of multiple vendors.

The Proof: Our integrated SMART Solutions bring your full life cycle — including regulatory, quality, clinical, reimbursement, and labs — under a unified governance structure. This helps you scale your program horizontally or vertically as your product evolves without onboarding new vendors or adding internal headcount.



"The most expensive regulatory path is the one you have to walk twice."

Outcomes, Cost, and Scale

Question 4: You're more expensive than our current CRO. Why should we pay more?

The Answer: If you only look at hourly rates, that might be the case. If you look at total program cost and risk, we are often the most cost-effective choice. Lower-cost options frequently lead to delays, rework, or additional studies. *The most expensive regulatory path is the one you have to walk twice.*

The Proof: We focus on getting it right the first time, reducing downstream issues, and protecting your timelines. By leveraging first-time-right medical device regulatory consulting services and proactive regulatory alignment, we eliminate the unknowns that lead to costly delays.

Question 5: What makes your labs different from a standard provider?

The Answer: Most labs are commodity providers. RQM+ (via Jordi Labs) integrates lab science with regulatory strategy. We don't just give you a report; we give you a submittable toxicological risk assessment.

The Proof: Our chemical characterization data stand up to the most rigorous FDA scrutiny. We've rescued stalled IDE submissions where previous labs failed to provide the level of identification and documentation regulators require.

Question 6: What happens if we need to switch mid-program? How do you de-risk the handoff?

The Answer: We start with a rapid assessment of your program to understand risks and gaps. From there, we establish a detailed transition plan and work closely with the existing team to transfer knowledge. Our focus is maintaining continuity while quickly stabilizing any areas of concern.

The Proof: When something goes wrong, like a regulatory setback or study issue, we focus on root cause, taking corrective action with clear communication. The goal is always to resolve the issue and prevent its recurrence while protecting your overall program.

Move Beyond the Checklist

Don't settle for a vendor that only checks boxes. Partner with a specialized MedTech CRO that provides you the clarity, control, and execution required to drive your strongest outcomes.

Schedule a strategy call with *The* MedTech CRO and make MedTech happen.