CASE STUDY

Get expert guidance to ensure your clinical trial strategy is set up for efficiency and success

Discover how Kathleen Wisemandle's strategic guidance helped RTx Resuscitation Therapeutics understand the full landscape of drug trials, including how to **identify and mitigate risk, select the right vendor,** and **create an operational strategy** that promotes success

"Kathleen is unique because she has lots of experience with large pharmaceutical companies yet provides strategic guidance in a very high-touch, personalized way. As a smaller company, her knowledge is very valuable to us. She helped us understand the wide range of details and intricacies that are involved in clinical trials."

IYAD AYOUB
COO, RTx Resuscitation Therapeutics

When RTx Resuscitation Therapeutics first began working with Kathleen Wisemandle, they were just starting their Investigational New Drug (IND) Application to submit to the U.S. Food and Drug Administration (FDA).

It was the first time RTx — a startup focused on developing and commercializing new therapies and strategies for resuscitation from life-threatening medical emergencies — had gone through the IND application process or completed a clinical trial.

And even though RTx's founder Dr. Raúl Gazmuri has decades of preclinical research experience and their Chief Operating Officer Dr. Iyad Ayoub had led the establishment of two contract research organizations (CROs), navigating the world of clinical trials as a drug sponsor was something completely new.

So when they were introduced to Kathleen and realized they could get strategic guidance from an early clinical operations expert who had planned over 20 INDs and First in Human studies, they jumped at the chance.

> "We especially liked that Kathleen had industry experience with large, well-established institutions," Iyad said. "We're a smaller company but our end goal is the same, which is to have a drug approved. We knew Kathleen had plenty of experience to help us do that."

So, RTx brought Kathleen in to help them understand the full picture of the clinical trial process and to advise them on how to strategically plan for their trial and meet the recommendations of the FDA.

After getting to know RTx and the drug they were aiming to have approved (which is a new indication of the drug erythropoietin), Kathleen took them through an extensive **Quality by Design** process that outlined every single aspect of applying for and running a clinical trial.

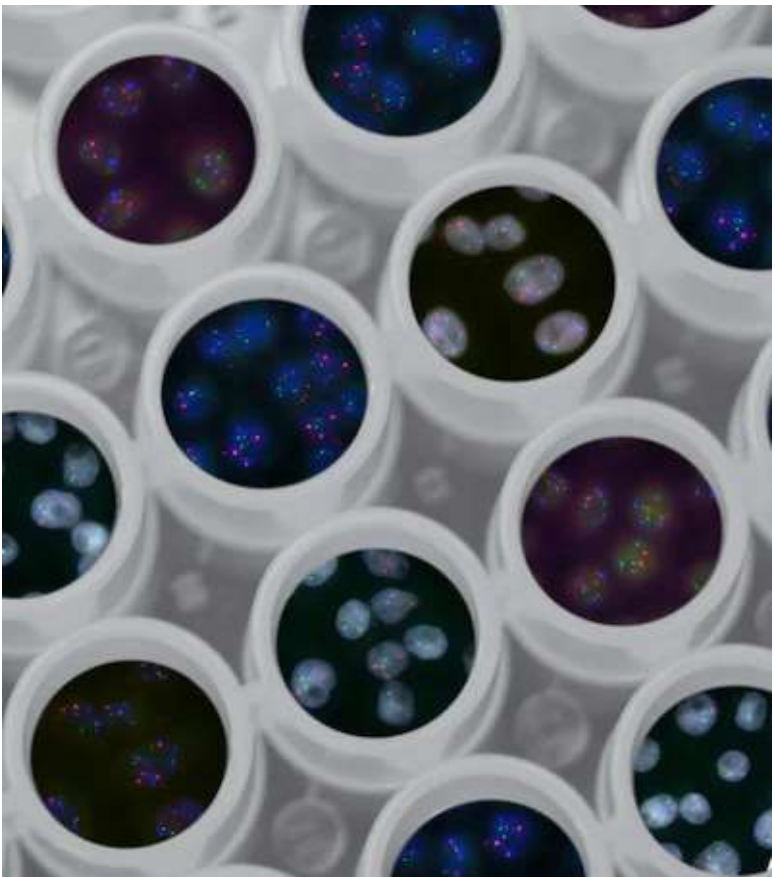
For RTx specifically, that meant focusing on their Phase III trial, since they were studying a new life-saving indication for a new patient subset and emergency use setting.

Kathleen's **Quality by Design** approach involves three main components:

1. A thorough **impact assessment** that helps companies consider the myriad of ways their clinical trial and their drug could have an impact on patients.

2. A **risk management and mitigation assessment** to ensure companies have considered, identified, and planned for all of the potential risks that could present themselves throughout any portion of the trial and how they might react should anything go wrong.

3. **Strategic guidance** on selecting a vendor or vendors for the clinical trial so that a company is getting the right scope of services for their specific needs and the right mix of vendors.



Iyad said going through the Quality by Design approach was illuminating, and provided them with a wealth of information and strategic feedback to guide the planning and execution of their clinical trial.

> "This is the first time we've created a drug, and we definitely knew there were things we didn't know. Kathleen helped us understand the wide range of details and intricacies that are involved in clinical trials, and consider everything about our clinical protocol on a much deeper level."

One area that was especially impactful for Iyad was the way Kathleen helped RTx think through risk.

"She really opened our eyes to the risk mitigation for our trial," Iyad said. "I knew we had to do it but she presented it so comprehensively on paper in a way I'd never seen. It definitely brought many things into our awareness that we were going to have to think through and plan for."

Iyad said the thorough risk mitigation is critical for RTx in particular because of the complicated circumstances in which their new indication of erythropoietin would be used, as well as how expensive it is to obtain.

"The area of clinical research we're in is very complex, and the logistics are complicated because our drug is meant to be used in a life-threatening situation where a patient is unconscious. A paramedic often isn't able to get informed consent from a patient, so that alone requires a lot of risk mitigation and planning.

"Also, because the drug is very expensive, it needs to be handled properly and protected. Kathleen provided guidance about how to safeguard the drug throughout our clinical trial."

Iyad noted that Kathleen's expertise was also extremely helpful in regards to finding the right CRO.

Even though he'd built two CROs himself and was no stranger to the services they provide, Iyad said it was beneficial to have Kathleen's advisory on the specific type of CRO that would best meet RTx's needs.

> "Kathleen connected me with a CRO that I'm quite sure we'll end up doing our clinical trial with. Because of her vast clinical trial experience, she knew the right size CRO to direct us to, where we can get the proper amount of attention we need and the right services."

Having strategic guidance on selecting the right CRO — as well as thoroughly and effectively planning for the clinical trial itself — is absolutely crucial for a smaller company like RTx — because failing to do so could wipe out the business.

For context, a study by Moore et al. published in the British Medical Journal found the median cost of a Phase III clinical trial is $48 million (with a range of $20 million - $102 million), and an average patient cost of over $41,000 per patient when all costs are considered.

Choosing the wrong CRO can cost biotech companies **between $600,000 and $8 million each day that a product's development and launch are delayed,** according to a study commissioned by the U.S. Department of Health and Human Services.

And as for failing to plan effectively, a study from Tufts Center for the Study of Drug Development found that the median direct cost to implement a substantial amendment was $535,000 for a phase III protocol.

The study also found that 57% of protocols had at least one substantial amendment, but **45% of those amendments were avoidable.**

Iyad said that the time and money savings alone are obvious reasons to have Kathleen guide a company through their early clinical trial strategy, but there is also an additional benefit: the stress and overwhelm she saves a company's employees, too.

"In addition to her expertise, Dr. Gazmuri and I greatly appreciated how Kathleen communicated and shared information with us. She is transparent and clear, and she's someone you want to work with. That's so important to a smaller company because having even just one person who doesn't fit with the team can be disruptive.

"Kathleen integrates right in. Having her conduct her Quality by Design process and guide your early clinical trial strategy allows more harmony within the company itself because your team's normal workflow isn't disrupted.

"She not only helps your clinical trial run efficiently — she helps your whole company be more efficient." ☾

To learn how Kathleen can set *your* company's clinical trial strategy up for success, visit AspireToGrow.co.