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# Drug and Device Development Outsourcing 2.0

## Soaring Beyond the CRO

Sponsors are constantly focused on moving their products from development through commercialization as quickly and efficiently as possible. Historically, biotech, pharma, and device companies have largely depended on the hope that the science works and that a traditional clinical research organization (CRO) model is the "best fit" to reach the finish line. With the shifting landscape, a new degree of personalization and agility is required, one that is not typically available with rigid CRO models. To meet this need, a new service partner has emerged to make success easier and more certain: the Research Consulting Organization or RCO.

### The CROs Paradox

Since the 1990's "faster, better, cheaper" has been the mantra of life science innovators looking to advance an asset from development to commercialization as expeditiously and responsibly as possible. Clinical research organizations (CROs) have answered the call; fitting themselves operationally to support the industry's blockbuster ambitions and creating the rigidity in delivery models we observe today. This model favored the largest biopharma companies that could offer the volume and long-term partnerships that made the economics work.

What about the small and midsize (SMID) innovators focused on rare diseases, new devices, and other programs? Historically, they have found themselves relegated to the end of the queue, piecing together pivotal programs with the CRO's "C" team. When coupled with an unprecedented talent shortage across the industry, the situation for these SMID innovators has become untenable, forcing suboptimal partnering decisions, budget overruns, and delaying action. In addition, investor pressure must contend with an 80% probability of delay and 16% overburn in clinical trial delivery[1]. With smaller rare disease programs representing 40%[2] of the industry's pipeline, the "bigger-the-better" CRO trend has become incongruent with market needs. **This provides an opportunity for the industry to embrace a new service partner: the Research Consulting Organization or RCO.**

Trapped in scale-based economic models and the "need volume to make the numbers work" mindset, traditional CROs are stuck; often solving for "shift-to-nuance" by pushing extraneous services to help drive appeal (and margin). Paradoxically, although the clinical trial – the center of a CRO's universe – might be the largest cost for a development stage company, it's the "nuances" that Sponsors need that often have greater impact. Chemistry, Manufacturing, and Control (CMC) concerns, along with validation, product profile, and regulatory strategy issues frequently have more long-term importance on a program's success than the clinical trial itself.

Many CROs have tried to solve this by creating biotech arms to focus on the needs of smaller programs; however, these business units are still held accountable to the same economic frame as their larger counterparts and compete for the same internal (and external) resources. Meanwhile, smaller programs with challenging drugs, devices, or cell therapies still need one-of-a-kind responses that are designed to quickly move them through the development process and regulatory paradigm with the same consideration for cost effectiveness.

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[1] http://www.appliedclinicaltrialsonline.com/closing-variance-gap-challenges-clinical-trial-budget-management-andforecasting

[2] https://pharmaphorum.com/r-d/rare-disease-rd-one-step-forward-but-a-long-road-ahead/

## Answering the call, what does the client need?

Ironically, the solution can be found in the pre–mega merger CRO industry's history. Rewind a few decades to the CRO "big bang"; CROs quickly gained favor as the functional outsourcing solution for the pharmaceutical industry, with clinical monitoring as the most common starting point. These companies had a rapport with investigators and site staff. For example, the front-line role of a field-based clinical research associate (CRA) was expansive. They held accountability over their sites and felt ownership across the delivery of a study.

As these companies grew and as the outsourcing model proved itself from a cost and quality perspective, CROs had to find ways to be more efficient and scale operations. Responsibilities that were once under the umbrella of a single person, like the CRA, were distributed across several functions, creating a disjointed feel to an intended end-to-end, full-service experience. It used to be that one size did NOT fit all, but today, this is a differentiator.

Today, full-service solutions have taken the front seat in the traditional CRO's portfolio followed by Functional Service Provider (FSP) solutions, which offer discrete functional services. The latter sub-segment continues to be in high demand by larger Sponsors, whose programs reflect a myriad of delivery models and vendors. The FSP market alone is expected to reach $21bn USD by 2027, at a 7.49% CAGR[3]. However, given the narrower margin of FSP businesses, most CRO leaders see these deals as a strategic necessity, as tools to help position for the next big full-service opportunity.

However, that "full-service-first" model no longer meets the needs of most clients and sweeping change is needed. What if we combine the traditional arms and legs model with deep functional expertise and peer-to-peer medical and scientific collaboration?

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[3] https://www.marketresearchfuture.com/reports/functional-service-providers-fsp-market-10780

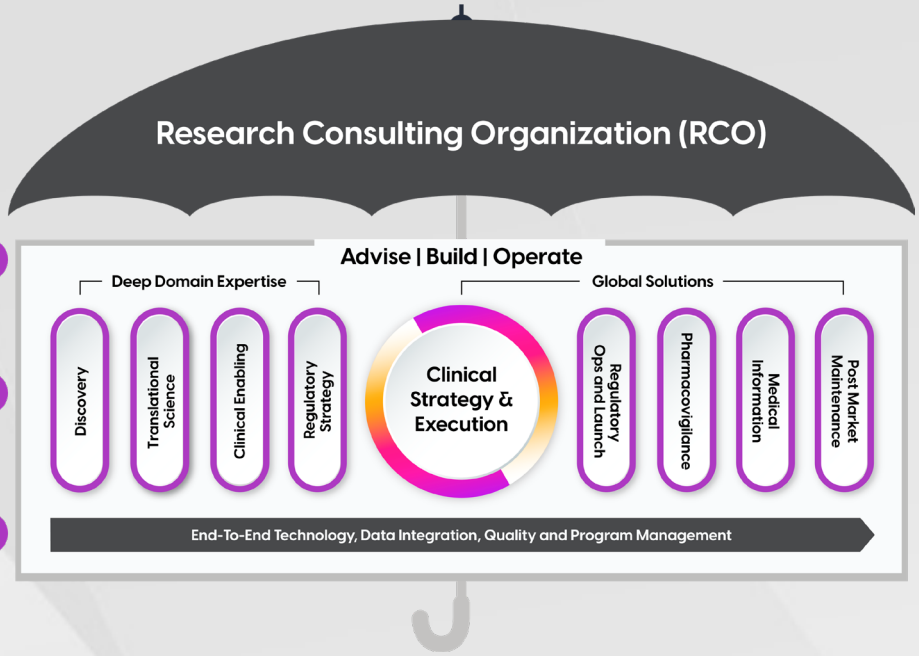
What if a partner collaborated to solve the strategic, scientific, and operational challenges of innovators as opposed to simply providing arms and legs? What if every client was provided a bespoke solution? A solution that may be simple and elegant, or global and of scale, depending on the distinct need.

At ProPharma we have built exactly that – **a fit-for-purpose solution** with the resources each Sponsor needs at any point in their development continuum. We call our new model a Research Consulting Organization (RCO). The RCO acts as the umbrella over distinct service offerings providing deep scientific and technical expertise assuring that as a Sponsor moves forward, they are well supported and expertly advised–winning against whatever situation they face.

As one example, our Regulatory Sciences service line encompasses deep regional expertise plus superior knowledge and executive leadership backed up with the tactical know-how to structure the most complicated trials and deliver results. This enables customized design and delivery of consulting solutions equipped to successfully navigate the increasingly complex global Regulatory environment.

## How it works

1. We support our clients by bringing targeted Subject Matter Experts (SMEs) to consult and advise on strategy, build the most efficient solution, and continuously support the product lifecycle for our clients.




Critically, we lead with consulting *(advise)* to co-create the optimal solution. Our experience has shown that this dramatically increases our client's probability of success and fundamentally showcases the investment we have made in our people who engage more broadly with our clients:

- *Advise:* Product development consulting with access to therapeutically aligned SMEs and data-driven decision making.
- *Build:* Assemble enabling operating model and related capabilities (people, process, and technology) to support the product development life cycle.
- *Operate:* Execute the plan, fully implementing and scaling the operating model through commercial and post-marketing phases.

2. Sponsors select from a comprehensive array of services to create a fit-for-purpose solution. These services by design operate autonomously in a federated model that can be engaged individually to help with a specific need or assembled into an integrated end-to-end construct that can flex up or down in scope/scale as programs evolve.

3. Reduce delays and drive consistency with dedicated, experienced program managers and asset strategists who choreograph the "dance" of data, systems, teams, and vendors to ensure end-to-end continuity and trusted high-quality evidence and experience.

## In summary

Today's product innovators need unique services to develop and commercialize their products and can no longer afford "faster, better, cheaper" as a mantra. We need a more thoughtful approach that focuses on risk, options, and quality throughout an asset's development.

Where traditional CROs push a full-service *"cookie cutter"* agenda, offering little compromise for the small Sponsor, ProPharma's RCO model leads with strategy to help de-risk programs and tailor solutions to maximize probability of success.

Each of our dedicated service lines tells a similar story of providing world-class critical consulting services that operate autonomously across regulatory, safety, technology, and operations, and are also able to perform as an integrated whole. This enables each function to continue to invest, innovate, and continuously improve to provide the right fit-for-purpose solutions for our clients.

Bottomline: ProPharma's RCO creates optimal outcomes and results and provides a real alternative for those Sponsors that find they just don't fit the mold.