# A Modern Guide to Clinical Operations Resourcing

How to Balance Outsourcing and Insourcing Models for Maximum Flexibility, Productivity, and Efficiency







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#### Summary

Facing an intensely competitive talent market, and growing pressures around productivity and cost, clinical teams are reconfiguring their R&D operations and organizational structures to get more done in less time with better outcomes.

While full-service outsourcing isn't going anywhere, especially as startups and small players continue to enter the market, companies experiencing rapid growth and those with more extensive R&D functions are moving beyond the "make versus build" or "outsource or not" questions to ask, "what is the best outsourcing, insourcing, or hybrid model for this situation?"

The blending of outsourcing and insourcing models is changing the types of scientific talent sponsor teams need and can lead to a strategic restructuring within their workforce. More sponsor organizations realize the downsides and vulnerabilities of outsourcing too much, and the risks of losing critical domain expertise to third parties. To guard against that risk, more pharma and biotech companies are bringing some competency in-house or deploying a more blended model.

While clinical leaders are making these resourcing decisions every day, few have taken the time to closely examine the specific factors that teams should consider when deciding to insource or outsource specific functions. There isn't a one size fits all model. In fact, clinical development is very dynamic, and flexibility is the only common feature of today's resourcing strategies.

This white paper explores the advantages and disadvantages of various clinical resourcing models in the current clinical landscape. While deciding on the optimal model for a given project is entirely dependent on the factors at hand, we offer several points to consider when framing the question in context. Think of this paper as a starting point for informed decision-making—a playbook for asking the right general questions at the outset of a project to determine the best path forward.



Need a reliable insourcing partner with deep clinical recruiting expertise and a global talent network? Let's talk.



We help companies fill in-house clinical operations roles and scale their teams as needs fluctuate with new R&D initiatives. Whether you manage clinical operations yourself, contract functions to outsourcing partners, or take a hybrid approach, we have the deep clinical expertise and extensive talent network to fill select roles whenever and wherever they arise.

We can fulfill clinical contracted and FTE resource placement needs in a variety of roles and functions including, but not limited to:



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- Get world-class capability and expertise at a competitive rate.
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We rapidly identify and place FTE candidates in a variety of positions and job functions. Our recruiters draw on extensive industry expertise to fully understand your hiring needs and conduct a rigorous identification and screening process to provide a shortlist of highly-qualified candidates, especially in specialized, competitive areas.

- Get rapid delivery of qualified candidates.
- Free up the time required to find and hire internally.
- Avoid candidate overload.

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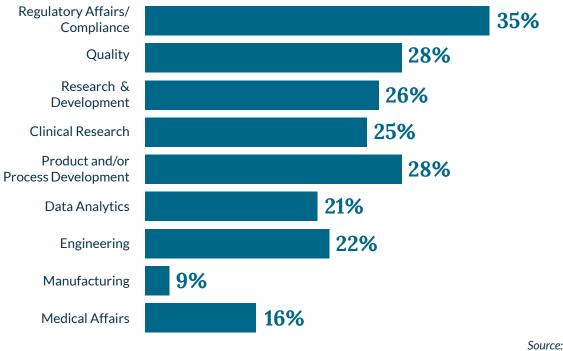
### Introduction & Background

Life science companies rely on a highly-skilled workforce of scientists, researchers, and other specialists to fuel their product pipelines. But as R&D activity accelerates across the world and demands more of a tightening labor market, maintaining a consistent source of human capital has become an enormous challenge.

Evidence of an R&D talent crunch has been accumulating for years. A PwC Health Research Institute <u>report</u> found that clinical executives had more difficulty hiring and were less confident in their ability to access top talent back in 2013.

Industry trade group PhRMA <u>expressed concern</u> over a "growing U.S. skills gap" in pharmaceuticals, estimating that two million positions will go unfilled between 2015 and 2025, mostly because of STEM talent shortages.

A 2018 <u>survey</u> of 354 life sciences hiring managers and human resources professionals conducted by the Coalition of State Bioscience Institutes found high-value positions like RA, R&D, and clinical research were among the most difficult to fill.



#### **Functional Areas with Difficult to Fill Positions**

2018 Life Science Workforce Trends Report, CSBI



All of these challenges are compounded by the changing nature of the industry itself. A host of business challenges are pressuring companies to curb expenses and find new efficiencies—all as studies become more numerous and complex. Some firms have found relief through consolidation, using M&A to build and scale in select therapeutic areas. Others are right-sizing their workforces and shifting to new R&D organizational models that challenge traditional talent resourcing strategies.

The once pervasive trend toward full-service transactional project outsourcing, for example, has since given way to more nuanced approaches that incorporate multiple outsourcing and insourcing models to reduce costs and drive efficiencies in the face of growing R&D workloads.

In addition to thinking more strategically about how and what they outsource, companies of all sizes are also making strategic investments in bringing specific competencies in-house, either on contract or permanently. Depending on factors particular to the company, product, and project demands, clinical teams are dialing in their own blend of models to strike the right balance of capability and efficiency from one project to the next.

With so much moving so fast, few have stopped to consider what each model and mix of models offer in today's landscape. Even fewer have taken the time to document the processes used to identify the most practical resourcing strategy given the unique demands, opportunities, and limitations for a given project.

That's precisely what we seek to do in the subsequent sections of this paper. Drawing on existing research and contributions from clinical subject matter experts who see this process unfold firsthand, we identify and briefly unpack the challenges around clinical resourcing before demystifying the current rationale for choosing various outsourced and insourced resourcing models. We then explore some key points to consider when making resourcing decisions in the context of a project.



## Challenges & Opportunities in Clinical Operations Resourcing

For decades, CROs developed some of the most effective and efficient systems and grew to a massive scale, giving them power in the marketplace. More recently, they have worked to recruit some of the industry's best talent from sponsors, academia, and regulatory agencies. Over time, however, the reliance on full-service CRO engagements has slid into an unhealthy dependence. In-house teams find themselves struggling to manage the activities of their providers without the internal resources to pull work back or surge for time-critical efforts. And despite the heavy and increasing reliance on CROs, sponsors still suffer from long cycle times, high costs, and lower than desirable success rates.

Historically, in-house sponsor teams suffered in two key areas. First, lean internal operations meant that sponsors sometimes lacked the functional expertise to proactively oversee and manage all aspects of outsourced work—quietly ceding power and leverage to CROs. This problem is still present today, forcing companies to spend millions of dollars on post-study standardization projects to format and harmonize disparate work products from various CROs. Over-reliance on sponsor program and project managers or procurement for vendor oversight means that subject matter experts at CROs don't get the clear direction on technical questions necessary to standardize across programs. It also means that sponsors may not understand whether they are getting quality and value on highly technical deliverables.

The second issue with lean sponsor operations is the inability to have a credible alternative provider in place. The prospect of "rescuing" an underperforming project from one CRO and moving it to another is very challenging for a team that is already lean. Internal expertise and capacity can provide a buffer or optionality in those situations. It also can ensure that there are sponsor subject matter experts available to relieve personnel busy managing CRO timelines and budgets.

Many recent studies have sought to pin down and better characterize the rifts in outsourcing that have prompted companies to rethink their approaches. One such analysis, a 2019 <u>report</u> from Tufts CSDD, concluded that outsourcing practices have widely been seen as "fragmented," "tactical," and inviting of the very inefficiencies they were supposed to mitigate.

A 2018 <u>study</u> from Pharma IQ looked even deeper into these sentiments, finding that the access to expertise, time, and cost efficiencies afforded by CROs often "come at the cost of duties such as intensive communication management, confidentiality concerns, and regulatory considerations."



This study also revealed an emerging belief among clinical leaders that some functions may naturally lend themselves to more convenient outsourcing while others are better handled—or at least better managed or facilitated—in-house. Among Pharma IQ's survey respondents from sectors including large pharmaceutical, biotech, and device companies, over half (53%) indicated that they fully outsourced their clinical monitoring function while far fewer reported fully outsourcing statistics, pharmacovigilance, and project management at 1%, 8%, and 10% respectfully.

Studies like these confirm that companies are evolving their resourcing strategies to balance several outsourcing and insourcing models that play to each's strengths and offer better functional management of outsourced activities.

" Today, it's not uncommon for a growing biotech company outsourcing their biometrics operations to need someone with the domain expertise to manage that outsourced work. The same is true of many other functional areas in clinical operations like safety, data management, and monitoring. Even mid-sized companies often need a few contractors or employees in that department to oversee and coordinate activities across CROs and ensure that work is standardized. Those resourcing investments often pale in comparison to the costs of remediating problems resulting from a project being under-resourced."

- MARK SHAPIRO

Life science companies of all sizes are increasingly recognizing outsourcing firms as strategic partners that can work faster and better within a blend of resourcing models that utilize in-house domain experts and external resources. The Tufts CSDD report referenced earlier found that firms now often use various models for singular tasks, functions, programs, and full-service arrangements. 42% of firms surveyed reported "routinely using" a staff augmentation model for clinical resourcing, for example, while 56% and 77% reported using FSPs and full-service outsourcing, respectively.

As these findings validate, hybrid approaches are affording clinical teams the flexibility that has become advantageous or even necessary for conducting complex studies at the efficiencies needed to keep pace and stay competitive. In practice, this often materializes as an intermediate layer of contracted or permanent functional experts



with the domain expertise and firsthand experience to oversee and manage CROs more effectively. In some cases, this "functional insourcing" model is scaled up to bring entire functions in-house and under the company's control, either through flexible staff augmentation (full-time contractors and consultants) or direct hiring (FTEs).

This approach offers unique advantages for companies of all sizes. For smaller organizations engaged in project-based outsourcing, filling functional leadership roles with expert insourced contractors and consultants enables broad flexibility, low overhead, and the ability to test particular professionals for possible long-term management and oversight positions if and when permanent needs arise. These functional leaders can also play a pivotal role as hiring managers when larger groups need to be staffed with specific skill sets.

Larger companies can scale this concept up to create an efficient mix of outsourced and insourced FSPs. In situations where a group of internal resources is preferred over an outsourced group, multiple contractors and consultants can be brought in to form an internal functional department that offers the flexibility of contracted service with the advantage of internal control and aligned incentives. With the right insourced resourcing partner—one that combines reliable clinical recruiting expertise with a deep pool of talent, companies can lift the burden on HR and more quickly resource their projects as needs fluctuate.

" In project-based outsourcing, you're seeing this layer of contractors, consultants, and sometimes full-time staff who are managing the CRO with a high degree of functional expertise. A Contract Project Manager or Contract Clinical Operations Manager will be functionspecific and ingrained as an extension of the company. For mid-sized or larger companies accustomed to outsourcing and interested in retaining a healthier level of functional expertise internally, functionally insourcing a department with a group of contractors can provide the leverage needed to regain balance in the relationship-likely reducing change orders in the process. In some cases, the question of whether or not an FSP's team will genuinely perform like they're 'your people' is a critical one. Insourcing a function can be an antidote to that risk."

– MARK SHAPIRO



The opportunity to lessen the reliance on CROs is particularly advantageous as R&D workloads grow and protocols get more complex. As many clinical leaders have realized, the more reliant a company is on its CROs, the more critical it is that those overseeing them have the domain expertise to effectively communicate details, set standards and expectations, and gauge the work being done.

#### " If you don't have someone who knows enough about the domain on your side of those relationships, it's very likely you'll end up spending more and getting less."

- MARK SHAPIRO

Regardless of how much or how little it's implemented, a functional insourcing strategy may also dovetail with steps companies are already taking to insource the technological and system-specific ownership of clinical projects—a trend that has emerged industry-wide.

44 Mid-sized and larger companies are insourcing more of their clinical technology; mandating CROs use their systems for better efficiency and control."

– MARK SHAPIRO

As companies continue to explore hybrid clinical operations models that balance the benefits of insourcing and outsourcing, an important question arises: **What** *factors should one consider when selecting a model or mix of models based on their relative advantages and disadvantages in the context of a particular project*?



### Determining the Optimal Resourcing Model or Mix

So, what goes into the decision to use a model or mix—and what balance to strike to make trial conduct faster, less expensive, and less burdensome? Familiarity bias is often the first significant factor. It's natural to rely on what we already know when making decisions for the future. But especially in this context, where traditional models may be ripe for disruption, it's all the more important to acknowledge and try to set aside the familiar and comfortable to openly consider new and better ways to work.

The other major factor is the project itself; expressly, the type and volume of functional activities involved, protocol complexity, existing competencies, and site locations, just to name a few. Given the extreme variety in these demands from product to product or study to study, this requires a diligent, honest evaluation of the details against each resourcing model's relative strengths and weaknesses.

A study that aligns well with a company's existing therapeutic area and internal expertise may lend itself well to functional insourcing via contracted full-time contractor/consultant (FTC) staff augmentation. By contrast, if a new or less developed function is required to support a more novel study outside of core competencies, outsourced FSPs will be optimal.

In a third case, a company pursuing an indication that is wholly new to which there is no internal knowledge or capability may likely be best suited to outsource most or all of the project to a full-service CRO, but also require functional leadership with the domain expertise to oversee and harmonize that work. In these cases, it's important to have sponsor representatives whose role is to become the internal subject matter expert and absorb knowledge and expertise from providers to maximize the sponsor's likelihood of success.

In the latter two cases, it is important to recognize that a sponsor runs the risk of paying CROs to become experts in the domain that the sponsor needs to be an expert. Recognizing and managing that risk is important for long-term program success. It's okay for the CRO to know more about an area than the sponsor on the first study or two, but later in the program, the sponsor should have equal or greater expertise.

Below, we've taken these broad considerations a step further to contextualize the features, advantages, and disadvantages of each model according to a project's needs.



#### **Relative Strengths and Weaknesses**

Often, the bulk of contracted R&D services falls to non-core activities while an internal team is built to manage high-value and highly-sensitive functions. Determining the details of what work falls where often starts by evaluating the timeline goals and relative level of control required for each component of the project.

The following general criteria can be instructive for making high-level strategic decisions about the best way to resource a project.



#### Outsourcing (CROs, CDMOs, and FSPs)

- Less complex sample/results work
- Relatively simple, welldefined, and established workflows
- Access to novel subject matter expertise
- Opportunities to gain from highly-optimized processes, systems, and SOPs
- Less time-sensitive results



#### Insourcing (Staff Augmentation & Full-Time Employees)

- A greater degree of control, using internal quality systems and protocols
- IP protection through internal oversight
- Immediate access to results
- Reduced time managing third parties
- Optimization of excess laboratory space
- Improved and timely communication of project deliverables
- More granular, resourcespecific flexibility



Generally, the less control needed—and the less that IP and speed are driving factors for success—the better the fit for outsourcing. Conversely, insourcing can be advantageous in projects requiring greater relative control, mitigating IP risks, and in some cases, accomplishing goals in shorter cycles.

The following chart attempts to break out the critical factors to consider across several specific outsourced and insourced models. These traits are by no means exhaustive or universal but offer a generic lens to view possible best paths forward when dissecting clinical projects more granularly.

Resourcing Model	Characteristics	Advantages & Disadvantages
Full-Service Outsourcing	<ul> <li>Most or all study tasks are outsourced</li> <li>Project/study management is outsourced</li> <li>The study is conducted according to the vendor's processes, systems, and SOPs</li> <li>Typically not fully staffed by dedicated FTEs</li> <li>Contracts are often based on milestones</li> </ul>	<ul> <li>Advantages</li> <li>Reduces task-specific management and coordination burden</li> <li>Cohesive integration of multiple services</li> <li>Enables innovation into novel areas</li> <li>Disadvantages</li> <li>Possible management and oversight overload negate cost and resource savings</li> <li>Unwieldy contract management slows admins</li> <li>Often inefficient across multiple studies</li> </ul>
Functional Service Provision (FSP)	<ul> <li>Companies outsource the entire function (e.g., data management, drug safety, clinical monitoring, etc.)</li> <li>Often utilizes the vendor's processes, systems, and SOPs</li> <li>Contracts are often arranged by unit or function</li> <li>Usually not 100% dedicated FTEs</li> </ul>	<ul> <li>Advantages</li> <li>Better incentive alignment around innovation</li> <li>May include volume discounting</li> <li>Opportunities for process improvement across projects</li> <li>Disadvantages</li> <li>More than one FSP can significantly complicate process handoffs and create risks</li> <li>Vendor coordination can heighten management burdens</li> </ul>



Resourcing Model	Characteristics	Advantages & Disadvantages
Staff Augmentation (Full-Time In-House Contractors/ Consultants)	<ul> <li>Search/staffing partner supplements client staff projects managed internally, including facilitation with outsourced vendors projects</li> <li>Often uses client processes, systems, and SOPs</li> <li>Resources are contracted via full-time equivalency (FTE)</li> <li>May offer on-site or remote resourcing</li> </ul>	<ul> <li>Advantages</li> <li>The requirement to use client processes systems, and SOPs makes it easy to scale up vendors without additional burden</li> <li>A single staff augmentation partner—and even a single contract—can be used to manage multiple projects</li> <li>Company keeps full control over project</li> <li>Access to 100% dedicated FTEs without traditional hiring overhead</li> <li>Can structure contracts to scale resources up and down as needed</li> <li>Deep clinical recruiting expertise reduces HR burden and risk</li> <li>Disadvantages</li> <li>Possible co-employment risks</li> <li>Less built-in incentive to innovate</li> <li>IT and training can carry additional onboarding burden</li> </ul>
FTE Recruitment	<ul> <li>Search/staffing partner supplements client staff projects managed internally, including facilitation with outsourced vendors projects</li> <li>Always uses client processes, systems, and SOPs</li> <li>Resources are brought on as full-time employees</li> <li>May offer on-site or remote resourcing</li> </ul>	<ul> <li>Advantages</li> <li>The requirement to use client processes, systems, and SOPs makes it easy to scale up vendors without additional burden</li> <li>High incentive to innovate</li> <li>A single recruitment partner can be used to resource multiple long-term projects</li> <li>Company keeps full control over the project</li> <li>Hiring managers can directly source staff via clinical recruiting partner</li> <li>Rapid identification and placement in competitive roles and functions</li> <li>Deep clinical recruiting expertise reduces HR burden and risk</li> <li>Disadvantages</li> <li>Overhead and payroll costs</li> <li>IT and training can carry additional onboarding burden</li> <li>Requires long-term functional needs</li> </ul>





Besides considering the strengths and weaknesses of one or multiple resourcing models qualitatively, looking back on performance and quality metrics can help inform decisions with hard data.

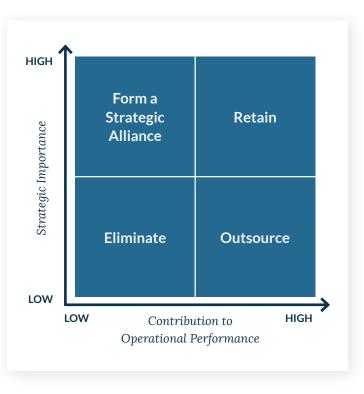
In addition to improving processes, analyzing KPIs and KQIs can also reveal opportunities to enhance broader decisions about which resourcing model or blend of models will best fit a project based on prior experience.

For example, slow turnaround times observed from a fullyoutsourced project may indicate that a company's internal systems and SOPs may be better suited for greater speed. In this case, some or all of the impacted functions may be transitioned away from a CRO and brought in-house, whether by augmenting staff with full-time contractors for a set period or bringing on an FTE for long-term needs.



## Creating a Simple Decision Matrix for Clinical Operations Resourcing

No matter how much a company stands to gain from enhancing its resourcing strategy, securing those advantages requires a resourcing process that accommodates change. Perhaps more importantly than confirming an industrywide shift in how clinical projects are resourced, the Tufts CSDD report referenced earlier concluded that only a third of clinical leaders say their resourcing processes are well-established. Even fewer-just one fifthdescribe their processes as highly effective.



A simple decision matrix can help logically arrive at the best decisions around outsourcing and insourcing. Each of the unique activities is rated for strategic importance and their contribution to operational performance.

Functions or more granular function-specific activities can be placed in each quadrant and resourced accordingly. It's important to note that this exercise is not thoroughly instructive for decision-making but rather a helpful starting point.





#### Strategic Partnership

These activities are strategically essential but contribute little to operational performance. Outsourcing is likely optimal but requires close oversight from a domain expert.



#### Insource

These tasks are strategically important and have a significant impact on operational performance. Consider retaining these tasks in-house to keep the maximum level of control.



#### FSP

These tasks are essential for successful operational performance, but have low strategic value. An FSP, either outsourced or insourced, should be sought to achieve high efficiencies at relatively little risk.



#### **Full-Service Outsourcing**

Tasks that are not strategically important and don't make a significant contribution to operational performance need the least oversight and management, and benefit the most from outsourcing.



### A Few Key Questions to Consider

Whether creating a formal decision matrix or planning resources another way, the following questions can help sharpen decision-making at the outset of a project.

## 1. How well are outsourced activities typically being coordinated?

If multiple outsourced partners are conducting work, there is very often an opportunity to save time and money by establishing an internal oversight function to proactively harmonize those work products by establishing and enforcing standards.

Closely examine past project metrics to identify possible opportunities where greater domain expertise could make work more efficient and proactive.

## 2. Who's paying for expertise, and who's benefiting from it?

It's not uncommon for companies engaged in project-based outsourcing (typically small and mid-sized organizations) to pay a CRO to become an expert in an area without absorbing those competencies themselves. When knowledge gained by experience isn't retained, companies become overly reliant on CROs whose personnel may not be available to apply that experience to benefit future projects.



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We often advise small and mid-sized pharma companies that if they're doing purely project-based outsourcing, it's easy to find yourself spending a lot of money to train people up at the CRO to be experts in what you're doing only to end up paying a huge opportunity cost in not owning that competency. They lose that organizational memory from one project to the next. If all of that information is owned by the CRO, which may rotate those people onto other projects, a company can find themselves with risks and costly rework. That can pertain to clinical operations, statistics, or any other functional area."

– MARK SHAPIRO

## 3. Are your CROs building relationships with investigators at your expense?

Many companies realize they need to invest in establishing relationships with investigators that are critical to their success, but end up outsourcing those relationships to the CRO. This can make a company dangerously reliant on those particular people for future studies, who, again, might not be available in the future for a myriad of reasons.

<sup>44</sup> Especially competitive, complex or very niche areas, it's really important to have somebody from the sponsor side participating in all those relationship activities. This way, even if a CRO is taking on all the work themselves, there's someone from the sponsor receiving that information by being present in key calls and meetings with investigators. Sites and investigators value those direct relationships with sponsors."

– MARK SHAPIRO



## 4. Could insourcing more flexibly scale to meet changing needs from one phase to the next?

While not necessarily tied to clinical research phases, a product scaling exercise may reveal a need or strong advantage in having the flexibility afforded by functional insourcing. If an internal data management team was preferred for a project, for example, starting by insourcing a data management leader and establishing trust in them at the outset of a project could serve as the stepping stone for scaling up resources to more functional hybrid approach later on.

When thinking about scaling resources throughout a project, a company may have one insourced functional leader overseeing a CRO in Phase 1. This person is both managing and overseeing the CRO and learning along with them. In Phase 2, the company might consider scaling up its internal expertise if needs emerge and just easily shrink that contingent workforce back down in Phase 3. This kind of functional insourcing gives you the chance to test resources and scale your program once you're confident in that leadership."

- MARK SHAPIRO



## 5. Are you experiencing any outsourcing "red-flags" to which insourcing offers a solution?

Insourcing is by no means an antidote to every outsourcing issue, but there are a few questions that often signal opportunities to invest in internal expertise.

#### These include:

- Frequent change orders or difficulty evaluating the merits of a change order
- Difficulty in coordinating details with outsourced partners
- Slower than expected study progress

- Budget overruns
- Chronic dissatisfaction in certain functions
- Sponsor teams receiving an overwhelming amount of work products from a CRO for review and sign-off (and thereby taking on responsibility for delays)
- <sup>44</sup> If a company struggles to answer a CRO's questions, that can indicate an internal gap that needs to be filled. Similarly, if a CRO presents a question they feel is important enough to ask, which does not inspire a strong answer, that can also indicate a deficiency in a functional domain. Difficulties in evaluating the scope or effectiveness of change orders are another big red flag. I'd also add slower than expected study progress. Sometimes that can indicate a sponsor struggling to understand some of the clinical operations nuances well enough to establish realistic expectations. Slow enrollment, in this case, might stem from a poorly-written protocol rather than a fault of the CRO."

– MARK SHAPIRO



## Key Questions at a Glance

- "Which model or hybrid approach will get our project done on time and on budget while balancing quality, speed, and cost?"
- "Are we managing our contracted relationships with adequate, consistent oversight, and regular interaction?"
- "If we add more outsourcing vendors or outsource more functional work, can we keep up with it all? At what point do internal resources need to scale to accommodate this?"

- "Are we retaining the competencies we're paying for via outsourced activities?"
- "How could more functional domain expertise improve outsourced work products proactively?"
- "How could a functional insourcing strategy scale by phase to make life easier for everyone?"



## Finding the Right Insourced Resourcing Partner

As many sectors of the life science industry continue to see dramatic growth, recruiting and retaining highly skilled professionals from a talent pool that's struggling to keep up has become an enormous challenge.

Today's hiring managers need to be able to scale staff up or down rapidly as project demands fluctuate—a never-ending balancing act between managing current resources and planning for future staffing needs.

These pressures have led companies to embrace the contingent workforce; highlyskilled individuals with expertise in rare and competitive fields who contract with organizations on a temporary basis. As firms are finding, this model often better reflects cyclical or project-based demand while infusing staff and systems with best practices gleaned from a variety of experiences.

But building and managing a contingent workforce can demand significant time and energy without the right resourcing partner—one that can take on the intensive work of finding talent and qualifying candidates around precise requirements.

Here, we explain three useful tips when looking for a life science resourcing partner that can help you find exactly who you need, when and where you need them.



# **1.** Find your niche. Are they generalists, or do they live and breathe life science?

Staffing and recruitment firms that work across a variety of industries often dilute their effectiveness in each one. The core issue here is that recruiters within these firms are often generalists themselves. Unlike a niche firm, whose recruiters must bring deep industry-specific experience to be successful, generalists often don't have the firsthand subject matter expertise to understand and articulate the fine points about the roles and functions that guide their search and selection process.



Without the expertise to make their clients' lives easier by narrowing 10 to 15 resumes down to five or fewer, generalists often can't avoid the cliche of throwing things against a wall to see what sticks. If a qualified candidate is even in the stack they provide, it's now up to the client to spend the time and energy selecting a winner.

Here at The FDA Group, for example, our recruiters and project managers come from the world they hire into each day. Unlike larger firms, we're armed with firsthand experience working in the roles where the subtle details make all the difference accelerating the process of finding great talent.



# 2. Ask about their search process. How do they identify and pre-qualify candidates to make your life easier?

Especially in specialized life science roles, a resourcing firm's job is to identify genuinely perfect-fit talent—not simply pass a stack of resumes back. Investigate how the firm finds and selects the resources they deliver as candidates to ensure they're more than just a job board.

What methods do they use to apply your requirements to identify potential candidates? Equally, if not more importantly: how do they sift through that group and work it down to a shortlist or even just one extremely qualified candidate you can be confident in?

Using ourselves as the example again, we have an extensive network of resources with established consulting agreements—some of whom are former FDA staff with intimate knowledge of requirements and expectations. If the perfect resource isn't found there for some reason, we immediately move to an active channel to source from many thousands more in locations all around the world, most of whom are not listed on job boards or other channels utilized by HR departments.

A few simple questions can go a long way in locating an effective resourcing partner:



"Will this firm push the real work back onto me by showing up with ten or more candidates? Or is this a firm that's so effective I can check their first one or two top choices and move forward without delay?" "How do they identify candidates? Do they have a bench of talent and active channels? Or do they grab a prepackaged template and blast it out to LinkedIn?"

"Do they work with talent sourcing partners in other countries to secure offshore resources?" **"Do they tout special software for identifying candidates?"** Be wary. These tools are often just flashy crutches to distract from lackluster recruiting skills. As of now, no magic tool—even with AI—can outperform an experienced resourcing professional who can discern soft skills through subtle, often intangible indicators.



# 3. Gauge their experience level. Do they have what it takes to fill specialized functional roles on your team?

Experience level often ties in closely to generalist versus niche resourcing firms.

"Are the recruiters tasked with finding a particular skillset still finding their stride professionally?" "Do they genuinely know the industry terms they're working with?"

This is a simple, but crucial point that often flies under the radar only to result in a messy stack of candidates that might be far from what you actually need. More resumes don't mean better candidates.



## We connect you to top clinical operations talent, wherever and whenever you need them.

Need to fill select clinical operations roles in-house? We rapidly identify qualified consultants, candidates, and contractors and connect you to them through the optimal workforce model.

Whether you need to fill a single role or multiple roles on your clinical team, we connect you to professionals with experience and expertise across all phases, therapeutic areas, and locations to augment and scale your in-house clinical operations team through contracted staff augmentation or a direct-hire arrangement.

We typically serve as a resourcing partner for companies that have brought or are bringing some or all of their clinical operations function in-house and are looking to fill select roles as needs fluctuate with new R&D initiatives.

Whether you manage clinical operations yourself, contract some functions to a CRO or FSP, or take a combined approach, we have the deep clinical expertise and large talent network to fill select roles whenever and wherever they arise.



#### We can fulfill clinical contracted and direct hire resource placement needs in a variety of roles and functions including, but not limited to:

Clinical Operations, Project	Biometrics & Data	Medical
Management & Monitoring	Management	Writing
<ul> <li>Clinical Research Associate</li> <li>Clinical Research Coordinator</li> <li>Clinical Research Scientist</li> <li>Clinical Trial Lead</li> <li>Clinical Trial Associate</li> <li>Project Manager</li> <li>Clinical Program Manager</li> <li>Technical Writer</li> </ul>	<ul> <li>Clinical Data Associate</li> <li>Clinical Data Manager</li> <li>Clinical Data Coordinator</li> <li>Biostatistician</li> <li>Clinical Programmer</li> <li>SAS/Statistical Programmer</li> </ul>	<ul> <li>Medical Writer</li> <li>Medical Communications</li> </ul>



#### **Staff Augmentation:**

Get contracted full-time consultant (FTC) staffing support and functional outsourcing for specified or open-ended engagement durations—a flexible, convenient alternative to traditional hiring.



#### **FTE Recruitment:**

We recruit FTE candidates with the experience, skills, and background to fulfill a variety of critical roles and functions that have become difficult to fill in a tightening labor market.



Learn more and connect with us. <u>Get in touch</u> »