

The upward trend of FSP outsourcing

How sponsors can meet staffing demands to keep pace with thriving pipelines

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Clinical research activity is surging

Predicted to expand 5.8 percent annually through 2030, the biopharmaceutical pipeline has nearly 400 therapeutics and vaccines in development.¹ This is good news for patients, who need the medicines we're bringing to market. It's good news for future researchers, who will build their findings on what we discover today.

But growth also means that clinical research professionals are in greater demand, from entry-level to expert-level staff. To meet urgent staffing needs, drug developers frequently turn to functional service provider (FSP) outsourcing.

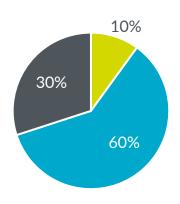
Parexel commissioned a survey of 30 decision-makers at mid-size to large biopharmaceutical companies in North America and Europe. Participants told us how they use FSP outsourcing now, and how they intend to use it going forward. We also heard about one common challenge faced by nearly all sponsors. We share our findings here, along with insight into that challenge and what we can do to overcome it.

1. View Research, 2022. https://www.grandviewresearch.com/press-release/clinical-trials-market

Getting in front of powerful workforce trends

The companies we surveyed all use FSP outsourcing, with a third using the FSP model for at least half of their total outsourced work. And 70 percent of all respondents expect to use the FSP model more frequently in the near future. It's a proven, cost-effective approach to managing workforces across portfolios. And as drug development continues to complexify, FSP partnerships deliver flexibility and know-how through rapid staff scaling.

In the next three to five years, sponsors say they will use FSP partnerships:



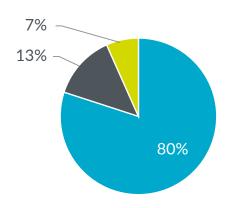
- Signficantly more
- Somewhat more
- About the same as now

The big challenge we face?

A shortage of candidates to meet hiring demands. Staffing is an issue throughout clinical research, where the supply of seasoned professionals just can't keep pace with the industry's growth. But the problem is particularly noticeable in FSP arrangements, which often call for speed and scale.

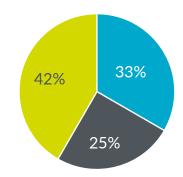
The clinical research talent gap could last at least into 2030.² In the past, with more candidates than open positions, our industry could hire as needed and remain relatively unimpacted by high staff turnover rates. In today's climate, however, clinical development can't expect the market to provide all of the skilled employees the industry needs, nor can we be complacent about turnover rates. Instead, we need to adopt new talent strategies, with sponsors and CROs working cooperatively to attract, develop, and retain staff.

FSP Staff Availability



- Experienced some shortage of staff availability and talent
- Experienced no shortage of staff availability and talent

Strategies Considered



- Remain focused on finding experienced resources
- Considering the modification of job roles and tasks to incorporate more junior-level staff (associate roles and interns)
- Starting to mix teams with more junior-level staff (such as associate

Of the sponsors we surveyed, 80 percent have been impacted by FSP staffing shortages, with gaps most pronounced in technical areas of clinical development. Respondents say they have also seen shortages within clinical operations and medical affairs.









Look at promising candidates earlier in their career

Recruiting in-demand staff means moving beyond our usual hiring pools. In our survey, one participant advocated for recruiting university students, making connections as early as possible. "We're looking for three to six months, 12 months or even longer before their graduation," said a vice president in Europe.

We've had success hiring students who lack clinical trial experience but are willing to learn through intensive internships. For example, Parexel partnered with several universities to recruit student interns for competitive one-year statistical programming placements. After two months of training, interns join projects on which they are supervised by mentors. Graduates who pass an individual assessment are invited to join Parexel as full-time employees. The majority of interns accept the invitation, and we are expanding the program to China, Poland, and the U.K.

By forging relationships with students prior to their graduation, sponsors and CROs can foster loyalty and fill recruitment pipelines with candidates who are already immersed in an employer's systems, processes, and culture.

Most Appealing Talent Candidates for FSP Hiring Needs



Think of talent development as an investment, not an expense

It's no longer realistic to assume the market will provide the specialized talent needed in clinical development. But if sponsors and CROs invest in training opportunities, we can cultivate the workforce we want.

We do some of that cultivation through the <u>Parexel Academy</u>, which offers role-specific and cross-functional education that can be tailored for sponsors and site needs. Programs are taught through lecture, scenario-based learning, and assessments by expert instructors who are active professionals in their field and bring

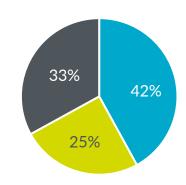
current, real-world experience to our programs. By investing in teams, we curb staff turnover while upskilling trusted people, training them to take on difficult-to-fill roles.

Our survey showed that sponsors would choose to hire experienced staff from ancillary functions or adjacent industries, or people with career gaps before hiring recent graduates — even graduates with relevant qualifications and training. Today's climate doesn't allow for such selectivity.

budgeting for more overall staff
hours as senior staff allocate some
of their time to mentoring and a bit
less time to performing the work
themselves. But overall costs will be
lower because junior workers are paid
at lower rates. With diligent oversight,
the team can maintain the expected
standard of quality. And as the
work progresses, the team's junior
workers develop into the experienced
employees we're all seeking.

On-the-job mentoring might mean

How have sponsors responded to a lack of experienced staff?



- Added more junior-level staff to teams
- Modified job roles to include more junior-level tasks
- Continued to seek experienced staff

"The lecturers are deeply experienced. The knowledge that I gained from the course gave me the boost that I needed to progress my career."

Parexel Academy graduate

The value of staff investment

What do candidates want most from an employer? When asked for their top five reasons for accepting a job in clinical research, **71** percent of new hires cited **future** career opportunities and **64** percent said they wanted professional development opportunities.

Source: Parexel International hiring feedback survey





"Being fully-dedicated to one client creates a family-like atmosphere for teams, which is the greatest retention tool. By adding career ladders to an FSP engagement, you add development opportunities to that tight-knit community – and further reduce the opportunity for high performing staff to leave."

Former CRA

Build in career advancement for FTE placement

To attract and retain talent, sponsors and CROs can create career **ladders** — maps of job roles and competencies that show how staff skills overlap, giving employees a plan for progress in their professional lives.

When sponsors offer career ladders by including multiple roles in their FSP outsourcing strategy, team members can build skills and advance without leaving the engagement. Career ladders create a clear path to promotion, which will entice new hires and improve staff retention rates. Given the right circumstances, some FSP staff will stay with an engagement for a decade or more, building a career as they work in concert with the sponsor's team.

Ladders also introduce employees to opportunities they weren't aware of or hadn't considered for themselves. So, if a statistical programmer develops an interest in biostatistics, her personalized ladder indicates which of her current skills would be relevant

to that new role and highlights areas in which she should pursue advanced training. This helps nurture new talent and allows employers to encourage high-performing employees to train for roles for which few candidates exist.

Currently, career ladders aren't the standard within FSP engagements. Creating them requires time and planning and an increased investment in staff. As labor shortages continue and likely worsen, sponsors and CROs need to pursue every possible path toward improving retention.

Another strategy for retaining talent: redesigning specific roles. Consider the CRA. CRA candidates are among the most difficult to recruit because they are in such high demand.³ To alleviate burdens on CRAs and make better use of other roles that are easier to hire for, let's rethink what a CRA's work should — and shouldn't include. Specialized workflows for administrative tasks can be assigned to junior staff instead of the CRA (i.e., processing investigator payments and participant reimbursements, providing site staff training, collecting, and managing certain site documents, and preparing ethics submission applications). This realignment would lessen the burden on CRAs and free them to focus on the patient and managing patient generated data flows.

For example, an initial assessment for a new FSP customer revealed that two overburdened senior roles - clinical scientists and senior study managers – were also responsible for administrative tasks on top of many other critical responsibilities. The customer accepted our recommendation to add two lowercost specialist roles to better align tasks to talent, resulting in significantly reduced labor costs. This task re-alignment saved the customer nearly 25% in one case and 10% in the other in annual labor costs and optimized productivity for both roles.

^{3.} Applied Clinical Trials, 2022. https://www.appliedclinicaltrialsonline.com/view/entry-level-cra-shortage-still-crippling-clinical-trials

Know what matters

What matters to employees today is drastically different than 20 or even ten years ago. And with competition for employees so fierce, your company culture is even more important to retain and attract high-performing employees. Employees want to feel valued, have professional development opportunities, have work-life balance, offer flexible working arrangements, and more. Organizations are now focused on Employee Value Propositions to clearly communicate the company culture they are trying to create.

Today's workforce is also more aware and involved in changing social issues such as diversity, equity and inclusion, environmental sustainability, and volunteerism. Having a well communicated Corporate Social Responsibility (CSR) strategy can help foster a sense of community, create a positive corporate culture, and increase employee happiness – resulting in higher employee retention and making it easier to attract new employees. For example, at Parexel we have carefully laid out our ESG (Equity, Sustainability and Governance) strategy on our website and detail our progress in a publicly available report.



"With so much movement in the industry, it's a great time for sponsors to make changes regarding updating roles. For example, if a senior CRA leaves, don't replace them with another senior CRA, but modify the role and consider a more junior CRA for the core functions."

— VP of FSP, Parexel

The future relies on creative and thoughtful solutions

To adapt to the current landscape, some survey respondents have revised hiring requirements or job roles so they can offer more positions to entry-level workers. About a third, however, still hold out for experienced staff.

There was a time when experienced clinical development candidates were easy to find, easy to hire, and easy to replace when they inevitably moved on.

Those days are done.

In a competitive market, success depends on our ability to adapt. Out of necessity, our industry has made numerous shifts: to electronic case reporting, to decentralized trials, to risk-based monitoring. Now eCRFs are all we use, and the majority of phase II and III trials include decentralized elements.⁴ Each of these changes has required sponsor investment. Fostering the next wave of our workforce is a similar investment: one with long-paying dividends.

The FSP partnership is another form of future-focused investment. In the immediate, the FSP model provides flexible resources and outside expertise. Then, as the partnership develops, FSP staff can offer deeper insights, develop process improvements, and generate greater economies of scale. Outsourced staff eventually become a seamless extension of the sponsor's team. By taking a long-term approach to FSP staffing and outsourcing, sponsors and CROs can address staffing burdens, set a shared course, and maximize the value of their partnership.

4. CenterWatch, 2021. https://www.centerwatch.com/articles/25878-hybrid-trials-may-overtake-traditional-studies-in-2022-new-data-show

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