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Functional Service Provider: An Emerging Paradigm in Clinical Trial Management

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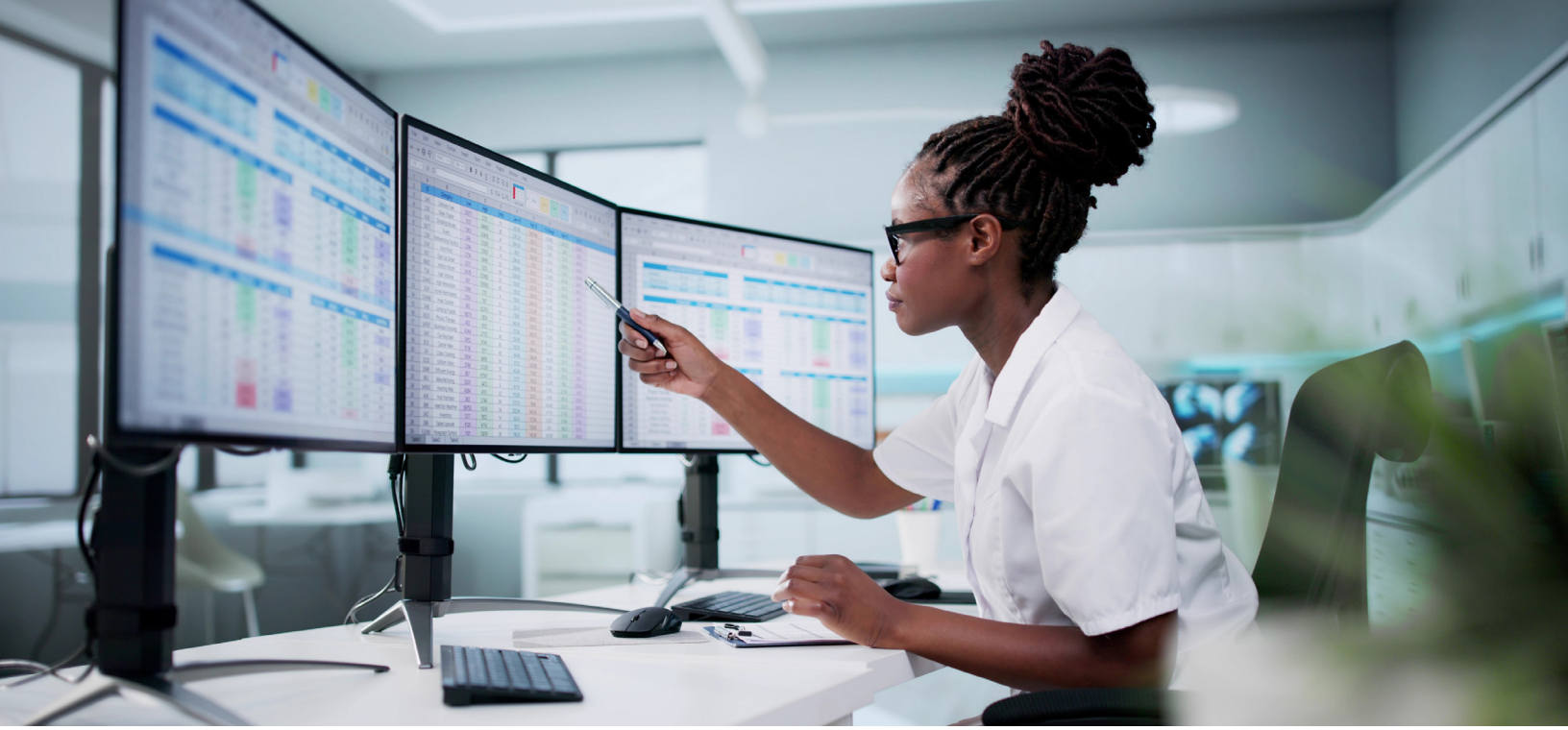

Functional Service Provider: An Emerging Paradigm in Clinical Trial Management

A growing number of organizations are positioning themselves as functional service providers (FSPs). This includes large global clinical research organizations (CROs) that have carved out FSP as a distinct business line, as well as smaller niche firms dedicated exclusively to this model. ProPharma Group, headquartered in Raleigh, NC, and a trusted partner in pharmaceutical services for nearly 25 years, has been delivering clinical FSP solutions side-by-side with its CRO services for much of the last half-dozen years.

ProPharma recently separated its FSP business, launching FSP Solutions under the leadership of President Kevin Wysocki, from its Clinical Research Solutions (CRO services) business unit. This offering focuses on core clinical functions such as biometrics, clinical and medical monitoring, project management, and document management. ProPharma can also lean on domain expertise to offer FSP solutions in areas like regulatory science, pharmacovigilance, medical information, and quality/compliance – though the immediate focus is clinical services.

“Market demand has clearly accelerated,” notes Wysocki. “Layoffs in Big Pharma over the past two years, combined with increased budget sensitivity across small- and mid-sized companies, have driven organizations toward the flexibility and scalability that FSP models provide. We believe this business will grow substantially over the next 12 to 18 months.”

Defining The FSP Model

In a landscape crowded with acronyms, what makes an FSP distinct?

Wysocki explains that FSPs occupy the middle ground between two extremes:

- **Full-service outsourcing:** Engagements based on specific assets or protocols, where talent, processes, and technology are outsourced wholesale.
- **Staff augmentation:** The placement of subject matter experts (SMEs) under full direction of the sponsor, typically using the sponsor’s systems and processes.

“An FSP is a hybrid,” says Wysocki. “We provide talent, oversight, governance, and in some cases, processes and technology. The goal is to deliver outcomes that

enable or support a clinical trial, not just a set of deliverables."

> Managing an integrated suite of services—from regulatory science and pharmacovigilance to clinical operations and digital platforms—requires thoughtful design.

For some sponsors, particularly smaller biopharma companies, ProPharma delivers complete functions under a governance framework, supported by KPIs and shared accountability. This flexibility allows sponsors to outsource clinical monitoring, biometrics, medical writing, or document management in a way that aligns with both budget and strategic priorities.

Integrated And Scalable Solutions

Managing an integrated suite of services, from regulatory science and pharmacovigilance to clinical operations and digital platforms, requires thoughtful design. ProPharma organizes its engagements as solution teams, led by project managers who understand the full pharmaceutical lifecycle. These teams scale dynamically as a trial progresses, flexing expertise where needed.

With global talent acquisition teams spanning the US, EU, India, and APAC, ProPharma ensures rapid access to qualified professionals. Recent industry layoffs have widened the available talent pool, but Wysocki emphasizes that ProPharma is selective: "We prioritize technical competence, cultural fit, and a long-term growth mindset. We are not a revolving door organization; we want our people to grow and build careers here."

Shared technologies and cross-functional processes help ProPharma avoid silos, ensuring data consistency and operational transparency across all service lines.

Tailoring To Sponsor Needs

ProPharma's FSP Solutions support both biopharma and medical device/diagnostic sponsors, whose needs differ significantly. Biopharma trials are broader and more complex, requiring diverse expertise across indications and therapeutic areas.

Device and diagnostic trials are narrower, often focused on demonstrating efficacy and safety or validating assays. Teams are typically smaller and require deeper integration with the sponsor's science and regulatory pathways.

Despite these differences, shared services such as document management and biometrics bring consistency and efficiency across engagements.

Why Sponsors Choose ProPharma

Organizations engage ProPharma for several reasons:

- **Experience:** Decades of expertise across the full pharmaceutical lifecycle.
- **Flexibility:** Ability to scale teams up or down quickly, whether one expert or a global team.
- **Breadth of services:** Support spanning discovery, late-phase clinical, and post-market.
- **Budget agility:** Conversion of fixed costs to variable project-based costs, enabling financial flexibility.

"The greatest value we deliver is in budget and team scalability," says Wysocki. "We understand the volatility of early-phase clinical trials and help organizations pivot quickly in response to success or failure. We speak clinical development fluently."

Case Study: Streamlining Study Start-Up

ProPharma recently partnered with a sponsor to oversee CRO performance during the start-up phase of a large, global Phase III clinical trial. Through embedded FSP resources, ProPharma:

- Oversaw study start-up activities across 13 countries.
- Achieved the activation of 35 sites and execution of 49 contracts within seven months.
- Established efficient processes for contract review, budget adherence, and approvals.
- Implemented an integrated site activation model that ensured accountability and overcame prior CRO challenges.

By embedding FSP oversight into the sponsor's operations, ProPharma facilitated a smoother, more accountable, and more timely start-up process, demonstrating the tangible value of the FSP model.

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