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Functional Service Partnerships:
Speeding Seamless Implementation

Establishing an FSP model, managing challenges, and how the role of implementation lead can assure efficient onboarding and resourcing for research projects.

While leveraging a functional service provider (FSP) model can be beneficial for sponsors, implementing them can be complex and challenging. Providing customized flexibility and scalability, standard or specialized services, FSPs can help fulfill various drug development needs to help improve timelines and costs. However, common pain points can include a significant investment in time and managing communication and expectations.

To help overcome these challenges, some contract research organizations (CROs) use an implementation lead (IL) to launch new projects. This role works closely with the operations delivery lead (ODL) but is more involved in the initial onboarding of resources. By adding an IL to support the process, responsibilities are divided, and efficiencies can be gained in the critical early phase of the partnership. This approach aims to drive better outcomes by providing a more focused level of effort in each key area of the partnership.

Lisa Beckel, Senior Director, FSP Solutions, PPD Clinical Research, at Thermo Fisher Scientific discusses keys to implement a FSP partnership, addressing some of the challenges, and how the role of IL can help assure efficient onboarding and resourcing for FSP clinical research projects. –KB

Contract Pharma: What is the process for establishing a functional service partnership model and how are responsibilities allocated?

Lisa Beckel: The goal is to partner with sponsors to create service models that are flexible and scalable to accommodate their growing pipeline, while maintaining the highest quality. The FSP model is fit for purpose—there is no "one size fits all." Critical to establishing an FSP model that successfully delivers is understanding the sponsor's vision and goals and applying the best approach to achieve those goals. Sponsors can customize their approach to FSP resourcing by contracting based on a service or task (i.e., unitized or deliverable based), or based on a model where resources are partially or fully dedicated to the client to perform work as the client determines (i.e., full-time equivalent, or FTE based), or may implement both in a hybrid approach. It's a matter of customizing the FSP solution for each sponsor to provide them with the desired balance of direct functional oversight, visibility and ownership of their projects, and access to a scalable and flexible workforce.

The FSP provider brings experience and expertise across all resourcing models to establish the FSP model by:
- Providing insights to the sponsor on the benefits and risks of the different models and what may best align to their specific pipeline and resourcing needs (e.g., considerations

for geographic placement of resources to reduce cost while maintaining the highest quality).
- Thoroughly understanding the sponsor's organizational structure, escalation and communications pathways, and key touchpoints, and then aligning the FSP partnership team to the sponsor's organization to enable faster and smoother implementation of the model.
- Fully adopting the sponsor's culture and ways of working and embedding them within the partnership team.

These activities ultimately result in a fit-for-purpose FSP model unique to the sponsor, with a clear structure that places accountability and responsibilities at the appropriate levels within the FSP partnership team to drive efficient communication and decision-making, while securing seamless delivery of the FSP model.

CP: What are some of the challenges sponsors and CROs face establishing and implementing an FSP model?

LB: Challenges in establishing and implementing an FSP model can vary widely based on the sponsor's previous FSP experience and organizational structure. There are a few areas where sponsors and FSP providers more commonly struggle, which can influence the success of the FSP model:
- Sponsors may not be aware of the variety of ways the FSP model can be implemented, nor the benefits inherent in the different approaches that make one model better for their organization than another; essentially, they don't know what they don't know.
- Transitioning into an FSP model can require a significant investment of time from the sponsor to establish the infrastructure and governance, which can defeat the purpose of and FSP partnership.
- Launching into an FSP model requires significant change management within the sponsor organization to ensure internal stakeholders are invested in the model's success.
- FSP providers have a steep learning curve to rapidly understand and align to the sponsor's organizational structure and ways of working so they can provide the best guidance for setting up the FSP model for success.
- Lack of visibility into the sponsor's pipeline and/or resource needs can hamper the FSP provider's ability to proactively plan for resource ramp-up or implementation of specialized recruitment strategies, reducing the effectiveness of the FSP model.
- FSP providers may be held to high expectations for recruiting highly specialized talent or be held to very restrictive requirements for job roles, driving longer deployment timelines to sponsors.

Fortunately, these challenges are very manageable by ensuring:
- Selection of an FSP provider with demonstrated experience and success in implementing customized FSP models, partnerships and governance, and who has established imple-

mentations strategies and tools that remove much of this burden from the sponsor so the sponsor team can focus on what is critical for delivering their pipeline.

- Engagement from key stakeholders in building the FSP service model foundation.
- Incorporation of change management into the implementation planning.
- Both sponsor and FSP provider identify a single point of contact to manage communication and expectations within their respective organizations.
- Clear communication pathways and awareness of implementation activity timelines.
- Clear processes for providing regular three-, six- or 12-month projections of the sponsor's resource requirements to enable proactive talent recruitment to meet the demand.
- The FSP provider formulates a targeted recruitment and candidate vetting strategy based on a clear understanding of the sponsor's job roles, target talent experience profile and other key criteria so the talent provided hits the mark.

This level of planning has demonstrated success in FSP engagements by delivering efficient and rapid establishment of the FSP model so the required talent stream is recruited and deployed seamlessly. This approach reduces the burden for sponsors so they can continue to focus on clinical trial delivery.

CP: What roles do the implementation lead and operations delivery lead play in an FSP model?

LB: Meeting the challenge of establishing and maintaining successful FSP models requires focused attention from seasoned experts if the model is to be implemented efficiently and effectively. For large FSP programs, two key roles are included within the FSP partnership team to secure the successful implementation and oversight of the model: the implementation lead (IL) and the operations delivery lead (ODL). The roles of the IL and ODL are complementary: the IL equips the partnership for rapid successful implementation of the model, while the ODL ensures that success is realized and optimized in the evolution of the partnership.

The IL's remit is to work with key stakeholders to apply the sponsor's ways of working and build the infrastructure that drives the FSP model and talent recruitment machine, thus reducing the burden for the sponsor. The bulk of the IL's work is completed during the pre-award, kickoff and post-award processes. Over time, as the FSP model is running smoothly, the IL's work reduces and the model transitions into the maintenance phase and lifecycle management.

The ODL serves as the single point of contact for the sponsor and is accountable for aligning the FSP partnership team to the sponsor's structure, culture and ways of working. The ODL ensures the partnership team members work in a coordinated and consistent manner so that delivery and support of the resources is achieved, and that those resources perform to the agreed standards and targets. This work begins at kickoff and ramps up as the partnership and model are established and smoothly transition into the maintenance phase. The ODL oversees the ongoing lifecycle management of the model and partnership, including financial stewardship, proactive risk management, and rapid issue escalation and resolution.

This following diagram outlines how a typical FSP partnership team can be organized and the relationship of the IL and ODL within the team.
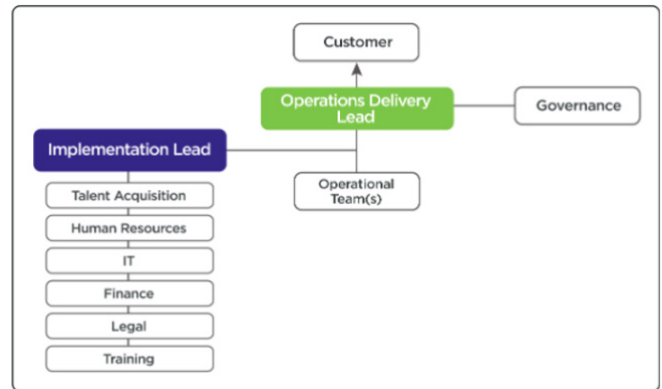

Figure 1: Typical organizational structure shell when utilizing implementation lead

CP: How does the IL role improve efficiency, onboarding and resourcing for FSP clinical research projects?

LB: Thorough planning and forethought are key to successful implementation of an FSP model. The IL develops and coordinates the cross-functional implementation strategy to ensure the process driven by the FSP provider is standardized to drive faster and more efficient onboarding, as well as thorough embedding of the sponsor's ways of working and culture into the partnership team. The IL, in partnership with the ODL, also assesses the existing partnership governance and oversight structure to determine how best to align with a multiple FSP provider model—should one exist—as well as providing input and guidance into creating a partnership governance if one is not in place. The IL can document decisions, processes and standards in a partnership handbook, which can be used to define the attributes of the partnership to support ongoing standardization of the agreed FSP model. This approach avoids startup delays while also off-loading much of the implementation workload from the sponsor so they can continue to focus on delivery of their clinical research projects.

Utilizing the IL's expertise ensures the model's processes are clear for the functional teams, that the sponsor's expectations are incorporated, and timeline commitments are achieved. The result is a high-quality output and a positive experience for the sponsor. Additionally, an efficient onboarding experience delivers quick integration of the new FSP employee into the sponsor team where they can begin to contribute and take part in meaningful work. This smooth transition and embedding with the sponsor results in a positive experience for the individual, greater employee satisfaction and higher employee retention, all while fostering a "one-team" approach. These efficiencies create a win-win outcome for both the sponsor and the employee. **CP**

LISA BECKEL, is a clinical research professional with 25 years of experience in clinical development spanning the CRO, pharma and biotech sectors. She has extensive experience in oversight of clinical programs in both full-service outsourcing models and functional service partnerships, as well as collaborating with sponsors to implement and successfully deliver in these models.