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Breaking Barriers:

Strategic Use of FSP Models to Expand Trials into Non-Footprint Countries

Leveraging functional service provider models to enhance global clinical trial reach and inclusion.

One emerging de-risking strategy to address the intense competition for patients at clinical research sites is the expansion of clinical research into "non-footprint" countries where drug developers lack a physical presence. These regions, often found in emerging markets or remote areas, provide access to untapped patient populations. Leveraging research sites with lower clinical trial activity allows drug developers to benefit from more consistent enrollment and heightened engagement from staff.

Expanding clinical trials into non-footprint countries poses considerable challenges. Beyond the challenges associated with establishing operations in any new region, expanding into these countries means navigating regulatory landscapes with nuanced country- and region-specific regulations, overcoming language and cultural barriers, handling logistical complexities, and building relationships with local sites and vendors. Cultivating these relationships requires an understanding of local cultures, business practices, and expectations. Similarly, recruiting and hiring local staff necessitates compliance with location-specific hiring practices and local labor laws.

HOW FSP ENGAGEMENTS IN NON-FOOTPRINT COUNTRIES CAN DELIVER ON SPONSOR GOALS

To circumvent the many challenges involved in expanding trials into non-footprint countries from scratch—as well as sustaining that research infrastructure over time—many biotech and biopharma companies are turning to functional service provider (FSP) partnerships that offer established global operations to gain access to a wider clinical research population.

These FSP partners source and manage experienced local professionals who not only possess fluency in the local language but also have existing relationships with local research sites, key opinion leaders, vendors, supply chains, and other stakeholders. FSP partners with established global operations also possess crucial insights into local medical practices, regulatory frameworks, and regional standards of care. This com-

bination of necessary infrastructure, in-country understanding, and extensive professional networks enables sponsors to quickly launch and efficiently scale clinical trial activities in non-footprint countries. It helps them meet aggressive timelines while maintaining adherence to local regulations and seamless cross-country collaborations.

Part of the appeal of an FSP partnership is that it allows the sponsor to retain a sense of control and facilitate oversight. Even in cases where the developer may not have direct visibility into a specific country, FSP partners can create a customized country management and oversight structure that ensures the sponsor's compliance with good clinical practice (GCP) requirements for effective oversight.

One common misconception is that the expansion of clinical trials outside of a drug developer's global footprint is usually reserved for "rescue" operations. While, in fact, using non-footprint countries in rescue strategies can be very effective, expansion does not have to be a harried, "last resort" effort to mitigate for an insufficient recruitment pool or timeline delays. Expansion to non-footprint countries has proven to be a very effective proactive measure that allows companies to deliver on clinical research goals in a model that can promote quality and trial excellence.

STRENGTHS OF A CUSTOM FSP OUTSOURCING MODEL FOR NON-FOOTPRINT COUNTRY EXPANSION

The FSP model, in which all or most of a single function (such as clinical operations, pharmacovigilance, data management, medical writing, regulatory affairs, etc.) is outsourced to an external partner, is a popular choice among sponsors looking for resource flexibility. By outsourcing individual functions (one or multiple) for either a trial, a program, or a portfolio of trials, drug developers retain control and complement their existing strengths with an outsourcing partner's deep bench of resources and clinical development expertise.

While some clinical trial operations, such as data management and biostatistics, can be conducted remotely, others require localized expertise and a physical presence (e.g., clinical monitoring and regulatory compliance support). As an example, clinical research associates (CRAs) deployed from footprint countries to non-footprint countries face challenging language and cultural differences. FSP partners that provide local professionals in non-footprint countries are better at mitigating these challenges while simultaneously integrating with a sponsor's existing structure and systems.

Another benefit of employing an FSP model is that it isn't a one-size-fits-all solution—every arrangement is tailored to the unique needs of each sponsor and project. By approaching expansion into non-footprint countries using the flexibility and adaptability of an FSP model, sponsor needs can be met in a dynamic and efficient way that nimbly accommodates changing demands and unanticipated challenges. Whether it's a planned expansion of clinical trial or a rapid deployment to accelerate or rescue a project timeline, FSP partners with established global operations are ideal partners to deliver customized solutions that meet specific sponsor needs and fill gaps in resources and capabilities.

A well-established global FSP partner also plays a vital role in assessing the feasibility of an arrangement to reach specific goals in non-footprint countries. Based on its local expertise and experience, the FSP partner should offer forecasts for enrollment in certain countries or regions of interest, enabling the sponsor to understand the options that would be the best investment of time and money. Then, based on these forecasts, the FSP partner is also well positioned to identify and deliver the resources needed for these countries—from providing a few employees to filling a small gap in capabilities to outsourcing some or all of one or more functions.

Because an FSP arrangement in non-footprint countries can take many forms, providers that offer different contracting models should be identified to meet a sponsor's needs in the most cost-effective way. For example, full-time equivalent (FTE) staffing can support high-demand workloads, while partial FTE personnel may be better suited when workloads are low or variable. FSP partnerships also can operate on a unitized model, in which contracts are approached on a per-task or per-deliverable basis for a flat fee. And because the scope and demands of any FSP engagement changes over time, scalability and flexibility must be at the heart of creating and maintaining the relationship.

As biotech and biopharma companies come to appreciate the innate flexibility and value of FSP relationships, including the potential to leverage the model to expand to non-footprint countries, the FSP market has grown substantially. A 2023 survey of biopharma and biotech leaders revealed an increase in FSP outsourcing over the past two years with 41% of respondents reporting increased use of FSP models.[1] FSP growth is projected to continue at a compound annual growth rate exceeding 8.6% from 2023 to 2032.[2]

SELECTING A PROVEN FSP PARTNER

A strong, strategic FSP partnership with well-established global operations enables drug developers to tap naïve patient populations, maximize the financial and operational efficiencies gained by extending their geographic footprint and maintain trial quality. Choosing the right FSP partner is critical for successful outsourcing across locations and time zones. Here are key factors to keep in mind:

1**. Global presence:** Because circumstances evolve and needs change, by selecting a partner that offers an established global footprint with a broad and deep portfolio of services in non-footprint countries, drug developers can ensure their clinical development needs will be met every step of the way with high-quality resources. Access to a large pool of

professionals across different regions also ensures seamless operations. Ideally, partners should support both single- and multi-country umbrella arrangements to ensure clients can scale their global reach.

2. Regulatory compliance: Competency in navigating complex regulatory landscapes is essential to ensure smooth operations and adherence to regional-specific guidelines. Ensure that the FSP partner has in-country medical and regulatory expertise to provide local intelligence and a deep understanding of local regulations – and confirm that they can adapt any processes as needed to meet the compliance requirements of these non-footprint countries.

3. Ability to quickly mobilize staff: While FSP partnerships are often employed as a proactive strategy to expand a company's global footprint, some arrangements are also urgent, last-resort solutions to meet enrollment goals or address compliance challenges. In rescue operations, access is needed to a wide candidate pool and established infrastructure to quickly deploy vetted and trained personnel. Whether you are proactively or reactively planning to expand trials to non-footprint geographies, look for FSP partners with robust recruitment, training, and deployment processes and a track record in the desired non-footprint countries. This ensures rapid deployment of experienced professionals who are familiar with local cultures, languages, and research sites. Strong professional development programs are also foundational, providing dedicated, in-depth education to ensure that FSP staff are successful in their specific roles.

4. Change management and dedicated roles: The FSP partner should have well-defined change management processes to smooth the transition to an FSP arrangement. Particularly when expanding into non-footprint countries, consistent processes, oversight, and high-touch communications are essential. This may entail assigning dedicated roles to coordinate critical functions and set up direct lines of communication that align with the client's internal management structure to set the engagement up for success from day one.

5. Quality focus: FSP partners should have rigorous processes in place to maintain high standards throughout the entire project. This includes adherence to regulatory guidelines, compliance with sponsor SOPs, and a culture of continuous improvement. They should also understand and define quality management indicators when expanding to non-footprint regions. For example, is the sponsor looking for specific key performance indicators (KPIs) in its arrangement to ensure that the FSP services are meeting expectations, or does the provider need to help identify meaningful quality standards in the work?

6. Flexibility: FSP partners should tailor their services to meet their client's specific requirements. A provider's ability to operate in different contracting models across many different countries offers cost-efficient solutions to varying challenges. It's also important for an FSP partner to scale their resources and operations according to changing needs. Clinical trials often require adjustments in staffing levels and resources based on the progression of the study. An ideal FSP partner will have the capability to quickly ramp up or down to accommodate fluctuating workloads.

Finally, biotech and biopharma companies should seek a provider who truly understands the FSP model is a partnership. This partnership should build on the internal DNA of a client and function as an extension of the client's company.

CONCLUSION

Expanding clinical trials into non-footprint countries is a strategic approach that can be facilitated through partnerships with global FSP partners. By collaborating with FSP partners, drug developers can tap into naive patient populations, high-quality resources, and gain on-the-ground expertise, even in regions where they don't have any physical presence.

However, selecting the right FSP partner is crucial for success. Pharmaceutical companies should prioritize FSP partners with global operations, extensive networks, and a strong infrastructure. A proven FSP partner will not only have the necessary expertise in local regulations and cultural nuances but also demonstrate a commitment to quality, seamless communication, efficient collaboration across time zones flexible approaches tailored to meet client needs, and a proven track record of meeting timelines.

As biotech and biopharma companies continue to appreciate the flexibility and value of FSP relationships, the FSP market is projected to grow substantially. By embracing innovative strategies and selecting the right FSP partner, companies can expand their clinical trials into new territories while maintaining high-quality services, adherence to regulations, and operational efficiency. **CP**

References

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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.