



Functional Support Services: The Experience You Need

You Can Flexibly And Easily Add Highly-Skilled Expertise

Functional Service Provider (FSP) partnerships offer pharmaceutical and biotech companies the ability to flexibly and easily add highly-skilled staff to their team in core operational areas such as project management, clinical monitoring, data management, biostatistics, medical writing, and other domains. Use of these services is on the rise, as sponsors look for increased expertise or staff in specific areas, support from highly-skilled individuals, and/or expanded geographic expertise.

We Have The Expertise You Need

For over a decade, Synteract has been providing functional support services to clients across the U.S. and Europe. From small scale support through large therapeutic development programs, Synteract's FSP model offers experienced, high-profile resources with leading industry expertise to deliver clinical studies according to plan. Whether you are a small biotechnology company, a top five global pharmaceutical company, or somewhere in between, Synteract FSP services can offer:

- Resources to accommodate your global, regional, or local resourcing needs
- Best-in-class resources by function, including:
 - Project Management (e.g. Project Directors, Project Managers, Project Assistants)
 - Trial Master File Management (e.g. TMF Managers, TMF Specialists)
 - Scientific and Medical Writing
 - Data Management and Programming
 - Biostatistics and Statistical Programming
 - Regulatory
 - Medical Monitoring
 - Safety Services
 - Site Contracts
 - Study Start Up
 - Clinical Operations (e.g. Clinical Trial Leadership, Clinical Monitors, Clinical Trial Assistants)

- Functional line management
- Expertise in a variety of therapeutic areas
- Extensive product development knowledge

At Synteract, our FSP programs leverage a number of critical factors to help ensure your project is a success. We provide:

- A full assessment to understand your specific company culture and needs to ensure timely resourcing requests and excellent candidate matches
- Flexible, experienced, and skilled resources with a shared learning mindset
- Creative, customized options to address your needs, such as a mix in seniority levels, specific roles, on-site and offsite options, and more
- Highly proficient functional managers, trained on client SOPs, processes, and systems ensuring high quality oversight and delivery
- Key personnel at all levels within Synteract and at governance committees to regularly review long-term strategy, FTE forecasts, budgets, project statuses, and lessons learned for greater efficiencies
- Hiring by dedicated recruiters in partnership with Subject Matter Experts to ensure selection of quality candidates matching job and therapeutic requirements
- In-depth knowledge of country specific legal frameworks related to co-employment, local employment regulations, and labor law conditions
- Well-established onboarding, training, mentoring, and development programs
- Senior-level oversight, structure, and attention to delivery across the entire portfolio

For over 10 years, Synteract has established and grown a FSP model with a "Top Five" global Biopharmaceutical company. The FSP started with a small core team of Project Managers.

Addressing Our Client's Unique Requirements

Specific client needs included:

- Fast recruitment and onboarding of functional area experts in the client organization
- Navigating several client operational re-organizations and addressing related change management
- Ensuring functional line management of FSP staff
- Managing for successful growth

Our Solutions

Syneract provided:

- Dedicated recruiters to ensure selection of quality candidates matching job and therapeutic requirements
- An efficient onboarding process led by the Syneract Functional Managers. A detailed onboarding packet was created and Syneract Functional Managers organized regular one-on-one time to ensure efficient, effective onboarding of newcomers. A mentor was assigned to every newcomer leading to quickly up and running staff
- A mentoring program, in addition to all of the above. All FSP staff are organized yearly into small mentoring groups comprised of multiple functions. Groups are self-governed and meet every four to six weeks to share lessons learned, best practices, and to promote collaboration across functions and projects
- A robust governance framework. This included routine, joint governance meetings to discuss long-term strategy, operational success, challenges, resourcing changes, and metrics driving performance and planning
- Excellent understanding of the client's culture, needs, and changing environment. Syneract set up informational sessions/trainings for the FSP staff on the client organization, culture and expectations. Syneract FSP staff were motivated to implement new roles and responsibilities, demonstrated flexibility and embraced change
- Structured shared learnings and training. This included Global Team Meetings held every six weeks to address company updates, best practices, lessons learned, and more
- Ad hoc training throughout the year on specific topics and functions
- Highly proficient Functional Managers trained on client SOPs and systems. Syneract ensured proper scaling of line management to line up with team growth and to ensure consistent level of support for FSP staff

Program Success

- Syneract's excellent delivery and flexibility to adapt to the client's resourcing needs resulted in the opportunity to add multiple high profile, specialized resources
- Flexible, engaged resources demonstrating a shared learning mindset resulted in a solid team and low turnover
- Met or exceeded client performance expectations for both quality and operational delivery which led to contract extending over a period of 10 years
- To date, this FSP includes multiple roles and FTEs, supporting multiple global therapeutic development programs in Europe and the U.S.

About Syneract

Syneract is an innovative, full-service CRO supporting biopharma companies across all phases of drug development to help bring new medicines to market. Syneract has conducted 4,000 studies on six continents and in more than 60 countries, working with more than 26,000 investigative sites and 750,000 patients. It has contributed to more than 240 product approvals. Syneract offers a notable depth of expertise in oncology, general medicine, dermatology, and neuroscience indications, as well as rare and orphan, pediatric, and immunotherapy studies.

For more information on how we can support your clinical trial, please visit www.syneract.com/Services/Functional-Service-Provision or ContactUs@syneract.com.

Syneract.com

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