

CLINICAL OPERATIONS

PAREXEL'S FUNCTIONAL SOLUTIONS UNIT PROVIDES ACCESS TO:

- New and emerging markets and off-shore locations
- A global resourcing pool and dedicated talent acquisition team for rapid resources ramp-up
- A full spectrum of services and functional outsourcing solutions, ranging from staffing support to full department outsourcing
- Continuous process improvement and innovation
- Commercial terms that incentivize speed

With PAREXEL Functional Solutions, you get the highest quality services, where you need them, when you need them. That's flexibility.

For more than 30 years, PAREXEL has been leading the industry in providing innovative and customized outsourcing solutions to biopharmaceutical companies of all sizes to provide dedicated resources and expertise for functional outsourcing models.

PAREXEL offers services across a broad range of functional disciplines. Whether you must increase capacity temporarily or are looking to outsource an entire functional department – we have the expertise and global resources to handle the demand.

Clinical Operations Services

PAREXEL's Functional Solutions in Clinical Operations makes it easy for you to add clinical operations expertise and resource. Whether you are looking to address a short-term need or looking to fully outsource clinical operations process, PAREXEL can help.

Whether your team is assigned a new molecular entity, an entire portfolio, or your clinical endpoints change, you may need to shift your focus and prioritize your team's activities. Given the complexity and global nature of clinical operations, having the resources to join your team when you need them, where you need them is an important strategic advantage.

PAREXEL offer a full range of clinical operations services and specialist expertise to help ensure your clinical trials progress on schedule.

BENEFITS OF A FUNCTIONAL SERVICES PARTNERSHIP IN CLINICAL OPERATIONS:

- Keeps your resources focused on core business activity
- Dedicated staff recruitment team for a rapid resource ramp up
- Lean team structures to increase quality oversight, reduce bureaucracy and increase cost effectiveness
- PAREXEL's extensive global presence will enable Sponsors to get access to local resources globally
- Flexibility in providing different pricing solutions (FTE, Units, Milestones, etc)
- Highly experienced staff focused on delivering your project on time and on budget
- Access to PAREXEL's 30+ years' experience and dedication to continuous improvement and innovation

FLEXIBLE CLINICAL SOLUTIONS FROM TRIAL INITIATION TO CLOSURE

PAREXEL's Functional Solutions partnership in Clinical Operations offers you the full range of clinical operations services and capabilities to ensure your sites and trials are managed effectively, that your data is collected and recorded accurately, and that all of your activities comply with local regulatory requirements.

Clinical Operations services include:

- Study start up activities
- IBR and Ethics Committee submissions
- Site contract and payment management
- Clinical monitoring
- Filing regulatory documents
- Clinical supply logistics

We will provide you with complete flexibility to contract all or one of our clinical operations services, listed above.

Thanks to our extensive global capabilities, you will be able to access to one or all our clinical services in any region of the world.

PAREXEL's Functional Services model allows you to easily tap into a dedicated team of clinical operations personnel when you need them, where you need them, constantly supported by dedicated portfolio direction and oversight.

WORKING TOGETHER IN PARTNERSHIP

PAREXEL understands your need to select a partnership model that best aligns with your own development approach. For this reason, we offer several different models for Clinical Operations services designed to fit your specific needs. These include:

- **Insourcing/Staffing.** PAREXEL provides highly experienced staff that integrates with your own workforce to be managed by your team. This allows you to temporarily increase staff capacity, while maintaining program oversight.
- **Ad Hoc Functional Outsourcing.** PAREXEL fulfills your short-term needs for increased staff and infrastructure. Your research and development capacity expands and extends your global reach, precisely when and where you need it.

CASE STUDIES

- **Functional Outsourcing.** PAREXEL provides clinical operations services across multiple projects. Systems and processes can originate from either you or us. This approach provides team continuity that can produce enhanced quality and efficiencies.
- **Functional Strategic Partnership Outsourcing.** PAREXEL fully staffs and manages your clinical operations department and all their projects, so that you fully leverage PAREXEL's capabilities, infrastructure, and functional expertise. This model offers you the greatest opportunity to achieve efficiency, process improvements, drive innovation, and reduce cycle times.
- **Hybrid and Fully Customized Outsourcing Solutions.** If you need a combination of partnership models, PAREXEL will work with you to design a plan that suits your specific needs for quality, geographic reach, innovation and management control.

No matter which model you choose, you have access to PAREXEL's deep experience, as well as our worldwide therapeutic expertise, product development knowledge, process know-how, dedication to process improvements, and the high quality that you'd expect from one of the world's leading biopharmaceutical service companies.

We not only understand how to drive clinical operations forward,

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WE LOOK FOR PROCESS EFFICIENCIES TO SAVE YOU TIME AND MONEY.



CASE STUDY I

SITUATION

PAREXEL and a leading biopharmaceutical company entered into a monitoring partnership to cover some key European locations. Approximately 20 studies were assigned under the partnership, with staggered start dates. Over 50 FTEs were required within 6 months to be located across four European countries.

SOLUTION

PAREXEL developed a resource modelling tool that takes all data (number of sites, TAs, key milestones and regional/country allocation) and identifies the FTE need by region/country/function. By consolidating that data with existing information such as current staffing, PAREXEL was quickly able to propose a plan of action to the biopharmaceutical partner.

Then, through a dedicated recruitment team, a proactive ramp-up strategy was implemented, based on requirements, risk and contingency planning. The strategy included an ongoing candidate search process, where candidates went through almost the entire hiring process in advance of the need to expedite on-boarding time when required.

OUTCOME

Mobilizing the large, dedicated workforce needed for this program was a complex and demanding task. However PAREXEL were able to achieve this over a short time period, due to our strategic planning focus, extensive resource modelling experience, a dedicated functional solutions recruitment infrastructure, and established global operating procedures.

CASE STUDY II

SITUATION

PAREXEL and a global biopharmaceutical company established an integrated model for providing clinical operations in Asia Pacific and Japan. The sponsor needed to transition more than 50 studies and 600 investigator sites in just over four months. Over 200 staff, both legacy sponsor and PAREXEL were involved.

SOLUTION

PAREXEL developed a Functional Solutions Partnership with the sponsor. The sponsor decided to use PAREXEL's Clinical Trial Managers, benefiting from our commitment to operational excellence and innovation, helping to achieve greater trial efficiencies. Quarterly metric reviews were scheduled to identify potential risks, and actions to be taken to mitigate risk in advance.

OUTCOME

PAREXEL's flexible functional solutions helped the sponsor access specific expertise and resources as and when it needed. The Functional Solutions Partnership with the sponsor has gone from strength to strength, growing to over 300 FTEs.

We'll be happy to discuss your Clinical Operations needs, answer your questions, and discuss how PAREXEL's Functional Services capabilities can best support your project's success. For more information, please visit our website at www.PAREXEL.com, or contact a PAREXEL representative:

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