

Functional Service Provision (FSP) in Clinical Trials

MMS' functional service provision (FSP) allows you to add key expertise quickly to scale your internal teams according to development needs. Our staff can fill a range of positions in short or longer-term placements to support the design, analysis and reporting of your clinical trials.



The Challenge

A leading pharmaceutical company specified a requirement for an experienced biostatistician to provide statistical expertise in the design, analysis and interpretation of cutting-edge experimental research in the development of a vaccine. The right person was required to not only possess in-depth expertise on a broad range of advanced statistical techniques, but also be able to demonstrate strong time management skills and the ability to work effectively under pressure to tight deadlines as part of a large, interdisciplinary team.



The Approach

At MMS, we have a diverse team of experienced statisticians, programmers and data scientists with a wide range of expertise across statistical methodology, therapeutic areas and drug development phases. Following our approach to functional service provision (Figure 1), we were quickly able to offer a range of suitable candidates from which the Sponsor company's team could select the right person for the job. Educated to MSc level, the successful MMS candidate had over five years of experience as a statistician in the pharmaceutical industry. He had worked across multiple therapeutic areas including gastroenterology, immunology, oncology and neurology, and offered key expertise in propensity score methods and the use of simulation to inform clinical trial design. He was also proficient in the communication complex statistical principles to non-statisticians and so offered the perfect fit for the Sponsor's research team.

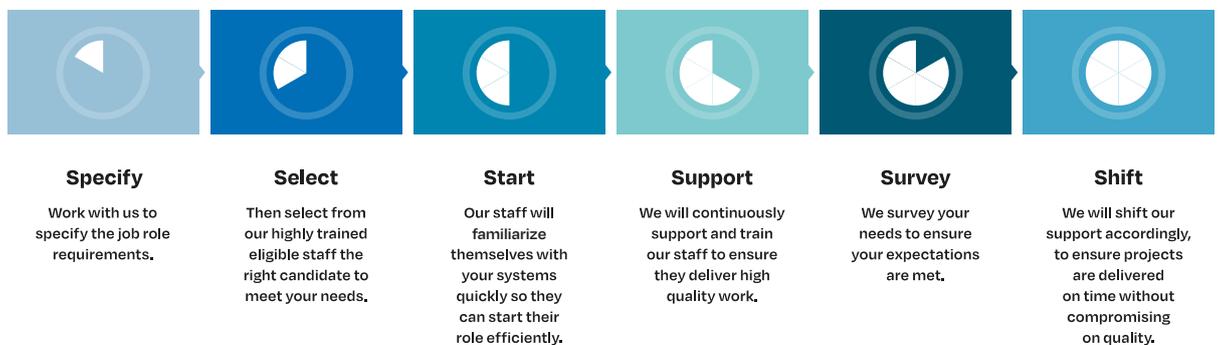


Figure 1. The MMS approach to functional service provision.



The Results

At the start of his new role, our statistician was able to hit the ground running as we provided key IT support and ensured that his GCP training was complete and maintained throughout the placement. This enabled him to integrate seamlessly into the Sponsor's large interdisciplinary team, adding key statistical expertise from day one. While working in this team, he was able to draw on further support around the required processes from other MMS colleagues placed on the project as well as external technical support from the wider MMS team, including Statistical Consulting.

Becoming an invaluable member of the Sponsor company's team, our statistician attended statistics and programming forums to share knowledge on new and challenging statistical methods. He routinely tackled the complex statistical problems faced by the group and facilitated the delivery of several key projects, involving collaboration across large teams to conduct and report complex statistical analyses for regulatory submissions.

As we surveyed the project needs over time, however, it became clear that further flexibility was required to meet the tight deadlines demanded by the project. Consequently, we worked closely with the Sponsor to shift the provision of statistical support to ensure that the project was delivered in a timely manner without compromising on quality. We did this by facilitating flexible working arrangements to align with the working hours of colleagues across time zones when required, ensuring continuity of personnel whilst maintaining our statistician's well-being.



The Impact

- Our statistician was instrumental in the successful, high-quality delivery of the project in a timely manner, and his performance quickly earned him an excellent reputation as an indispensable member of the team.
- His work contributed to the successful evaluation of a new vaccine, which was published in the high impact clinical journal, The Lancet.

Testimonials



He is often assigned the most challenging statistical problems faced within the department. In this regard he has demonstrated himself to be fearless, dedicated and excellent in his work. I am consistently impressed with the quality and speed with which he delivers results. I consider myself extremely fortunate to work with him, he is one of my best staff entrusted with the highest priority work and he deserves to be recognized as an excellent employee.

Head of Statistics – Large global pharmaceutical company



Lets talk!

If you'd like to discuss this case study further or learn more on how our biometrics services can support your development project, please visit our website:

mmsholdings.com