CROS NT
THE CENTRE OF EXCELLENCE FOR CLINICAL TRIAL DATA

Functional Service Provider Outsourcing Model
Why it is suitable for smaller companies, not just large Pharma

This article explores how biotech, small pharma and medical device companies should give consideration to utilizing specialist CROs for their non-core activities in place of recruiting, training and managing internal staff. It looks at how they could achieve more scalability and reduce costs by adopting an outsourcing model that mitigates against internal staff being too busy, or not busy enough, at different times during the year.

How can sponsors maintain control over their staff overhead, not to mention the staggering cost of clinical trials? One outsourcing model that has proved very successful for some large and mid-sized pharmaceutical companies is Functional Service Provision (FSP). This involves streamlining operations by function - Data Management, Statistical Programming, Statistical Analysis, Monitoring, Medical writing etc. - to improve efficiency and lower overall costs.

The FSP model facilitates a scalable, expert team of resources for a particular function and results in improved quality, eradication of change orders, reduced training and greater efficiency. Certainly large pharma have found it can reduce costs by up to 20%, but is this due to economies of scale, or should smaller companies be looking at this model too?

Small companies won't need a team of one hundred SAS programmers, but taking a mini FSP approach might be a lot more efficient than creating a small data management or statistical department, or seeking out freelancers when the workload increases. If you can have access to a scalable and broad range of expertise only when you need it, then it may make more sense to not recruit that programmer or statistician. It also avoids the risk of not having enough, or too much, work for a full time employee.

Using FSP, Sponsors can save on recruitment fees, training costs, and HR management time. The CRO is responsible for procuring the required resources and ensuring the continuity of trained resources. It also removes the risk of taking on a new recruit who turns out to be a bad fit. Using a CRO, the customer can easily swap out individuals that do not work well in the team without having to go through the long procedure of dismissal.

Perhaps the greatest advantage of small companies using a CRO as an FSP provider is that it allows the customer to build a relationship with the supplier, making them a virtual team that is familiar with their requirements, can plan ahead and be there for the long term. The CRO works better this way too as it can plan its resourcing knowing what is coming down the line. Specialist providers, rather than large CROs, tend to be a closer fit for small sponsors because they are more likely to be given the same team every time there is a new study, the level of attention is good, staff turnover tends to be lower, and they are less likely to be over stretched by preferred provider arrangements with the top 20 pharma.

Benefits of Functional Service Provider Model

- Scalable team, expert in Sponsor's system and processes
- Reduction in training requirements
- Continuity of trained resources
- Greater efficiency
- Improved timelines
- Control over overhead costs
- Consistent pricing
- Reduction in Sponsor's project management
- Lower recruitment/HR costs

How does the Functional Service Provision work?

A Sponsor must determine which functions are best suited for outsourcing under the FSP model. Ideally, Sponsors should outsource functions in which they are not experts and the activity is not a core competency of the company. In terms of clinical data services, this often includes data management, biostatistics, statistical programming, quality control, pharmacovigilance and medical writing. It is also best to outsource by product so that all the data for that product can be kept in the one place and in a consistent format. Sponsors can be involved in choosing the people from within the CRO for their project.

Considerations When Selecting an FSP Provider:

- Adequate capacity (sizeable team and not over stretched)
- Trustworthy and honest
- Good communication
- Low staff turnover
- Motivated staff
- Well qualified and experienced staff to ensure high productivity levels

Operational Efficiency

By outsourcing a particular function, a Sponsor can consolidate workload across projects - which can achieve up to 20% in time savings. The Sponsor can choose to take on the project management or outsource this too. Either way, operational efficiency can be achieved by coping well with the peaks and troughs and maximizing resource utilisation. A service level agreement should be put in place with the CRO so that expectations of productivity and quality are clear.

Cutting Costs

Cutting Costs. The biggest cost reductions are seen when drug development timelines are reduced through streamlining operations. The flexibility that comes with FSP puts an end to change orders and budget surprises. Since a certain number of resources are ring-fenced for a specific amount of time, it allows sponsors to know their financial outlay for 12-24 months ahead. CROs often offer discounted rates for ring-fenced resource so daily rates end up more favourable than for traditional fixed price contracts. It also allows the customer to see a benefit without having to sign a large contract because FSP contracts can be altered at any time to reduce or increase the resource, although usually with a month's notice.

CROS NT Functional Service Provider Model

CROS NT has an FSP infrastructure in place to provide resources that fit clients' needs - this includes teams of Data Managers, Biostatisticians, Statistical Programmers, Pharmacovigilance Specialists and Medical Writers. CROS NT also guarantees outstanding project governance, dedicating an FSP Manager to each function. CROS NT's IT team can ensure a secure connection with the sponsor's IT environment and provide a real-time reporting facility to allow sponsors constant access to study progress.

Quality Control Centre

CROS NT can act as a Quality Control Centre for incoming deliverables from high volume providers. The structure of our Quality Control service consists of a scalable team with training on the Sponsor's systems and processes with the ability to fix incoming datasets and produce ADaM documentation.

About CROS NT

CROS NT offers a centre of excellence for clinical trial data. We are an international Contract Research Organisation (CRO) specialised in biometrics including Biostatistics (methodology, programming and analysis), Data Management, Pharmacovigilance, Medical Writing and Training.

With over 800 studies completed, CROS NT has remained focused on biometrics as more and more clinical Sponsors are seeing the value in centralizing their data. CROS NT has offices in Italy, Germany and the UK.

CROS NT has an FSP model in place to allow Sponsors to counteract rising costs in the drug development process. The company maintains data quality by consolidating specific clinical tasks within a scalable team of resources.

CROS NT Functional Service Provider Model

Clinical Data Management

CROS NT has acquired extensive knowledge through the management of vast amounts of data generated by clinical trials. This enables the DM team to utilize tools, libraries and processes that make data management more efficient.

CRF Design, Review and Tracking	DB Design
Data Management Report Development	Data Management Plan Development
Development & Programming of Data Validation Specifications	Management of external providers and external data reconciliation
Data Entry	Medical Coding
In-stream Data Review	Discrepancy/ Query Management
Database Quality Control	EDC
Insourcing of Data Managers at Sponsor Site	CDISC SDTM Compliant Databases

Statistical Programming

CROS NT maintains a highly qualified group of SAS programmers to provide rapid production of tables, figures and listings. CROS NT is a CDISC Gold Member and can offer related services and consultancy for implementing SDTM and ADaM datasets for data standardisation.

Statistical Reporting	Data Listing
Statistical Consultancy	Presentation of Results
Creation of CDISC SDTM and ADaM datasets	ISS/ISE pooled dataset creation
ADaM Documentation: Analysis level, dataset level, variable level, parameter level documentation	Documentation SDTM: SDTM annotated CRF,SDTM metadata, DEFINE.PDF, DEFINE.XML
Statistical programming for TFLs using ADaM derived datasets	Mapping of studies from legacy to CDISC standards for ISS/ISE reporting and FDA submission

Biostatistics

CROS NT has delivered expert statistical analyses across all phases of drug development and in a wide range of therapeutic areas for over 20 years. Each analysis is conducted using validated and standardized procedures in compliance with regulatory guidelines.

Data Review: Planning, Meeting & Documentation	Randomization Management
Study Design	Protocol Writing & Review
Sample Size Calculation	Statistical Analysis Plan
Meta-Analysis	Filing and Reporting for Regulatory Submission
Statistical Consultancy	Integrated Summaries of Safety & Efficacy
Adaptive Trial Design	Bayesian Method

Medical Writing

A well-integrated cooperation between the Medical Writer and the Statistician, as well as rigorous quality control, ensures that the regulatory authorities will be satisfied with the final report. CROS NT has compiled an expert team of Medical Writers with decades of experience in both Europe and North America.

Clinical Study Reports	Common Technical Documents (CTD/eCTDs)
EMA and FDA Briefing Packages	Investigator Brochures
Statistical Analysis Plans (SAPs)	Integrated Summaries (ISS/ISE)
PSUR/DSUR	Posters
Abstracts	

Pharmacovigilance

CROS NT offers a case data entry, processing and reporting service for adverse events via a hosted safety database. It can also provide the installation & validation of Oracle AERS or Argus safety databases on customers' servers.

Low Cost Case Data Entry	Periodic Reporting
Adverse Event Processing	Expedited Reporting
Safety Narratives	Set-up & Management of a Global Safety Database
EudraVigilance registration & reporting	Risk Management Plans

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Tel Italy: +39 045 820 26 66
Tel Germany: +49 821 450 807-4
Tel UK: +44 (0) 1908 488822
info@crosnt.com
www.crosnt.com