



Clinical Trial Data Analysis – Optimising Services in a Globally Distributed Model

The growing complexities of the drug development process, toughening drug safety standards, increased regulatory scrutiny, and ongoing patent cliff have placed significant pressure on the pharmaceutical industry. An estimated \$217bn worth of originator products will have lost patent protection by 2018¹, with \$150bn of this figure predicted to be lost between 2010 and 2017².

In addition, with the number of blockbuster drugs coming off patent year-on-year, many innovators are increasingly examining how best to pick up the deficit. Emerging markets offer many opportunities for innovators undertaking this strategy, thanks to their spending power, potential for high volumes and offshoring capabilities.

Companies are also looking to employ new strategies in the product lifecycle process to bring products faster to market with new models, tools, technologies and processes. Better quality data and analyses set the stage for faster, more informed decisions. With about 85% of all therapies failing in early clinical trials, many being lost due to outdated and impractical clinical trial designs³, this is an area where significant improvements can be made in cost, quality and resources.

Biopharmaceutical companies who are able to establish global business models and overcome the challenges of limited drug development pipelines, cost pressures, time to market, patent expiry and changing regulations will beat out their competition. Successful companies are creating global business models and progressively turning to outsourcing to achieve their organisational and R&D goals.

Outsourcing in pharma has grown tremendously over the past decade⁴, and business process organisations (BPOs), knowledge process organisations (KPOs), scientific process organisations (SPOs) and contract research organisations (CROs) have been integral in addressing the industry challenges through providing clinical development services such as clinical operations, clinical data management, pharmacovigilance, regulatory operations, statistical programming and analysis and medical writing⁵. Amongst these services, the domain of statistical programming and analysis, or biometrics, requires a niche skill for service delivery. A global delivery model for this activity has distinct advantages when offshore delivery is effectively managed. This article will outline the requirements and rationale for outsourcing this activity, and will outline what is required to sustain and optimise the outsourcing of statistical programming activities in a globally distributed model wherein a majority of the delivery team is situated offshore.

Outsourcing Statistical Programming to Emerging Markets

Inappropriate study design and inaccurate analysis can make or break a clinical trial, can lead to wrong conclusions, and can result in significant cost and resource wastage. Hence getting the design and analysis of the clinical trials right is critical to the success of the development programme.

Biostatistics and statistical programming now accounts for around 7% of total clinical trial costs, with the outsourcing of this function having grown by 20% in the past three years⁶. The reason behind this rise in outsourcing is the growing internal costs, the growing requirement for computational and analytics skills and the mature domain capabilities that BPOs, CROs, SPOs and KPOs can offer. Indeed, pharmaceutical companies that partner with service providers stand to gain up to 50% cost advantage through globally networked delivery⁶.

Statistical activities such as study design, preparing the analysis plan etc. are primarily done in-house or by using onsite or onshore consultants. This is largely due to the preference for having the statisticians co-located with the clinical teams for close interactions, and also due to the paucity of resources with the required level of skill and experience available in the emerging markets. The small amount of offshoring of statistical activities which happens is mainly limited to captive units that the pharmaceutical companies have established in countries such as India and China, and even then, the type of work that is delivered from offshore tends to be mostly of low complexity. There are only a handful of service providers with the required expertise and experience to deliver complex statistical services from emerging markets such as India, China or Eastern European.

However, considerations for clinical programming are different. Due to the maturity the IT outsourcing industry had attained by the start of the century in countries such as India, pharmaceutical companies were keen to use the available infrastructure and resource pool to get their clinical trial programming work done in a cost-effective manner through a globally distributed model. Despite emergence of data standards and advances in software, clinical trial programming is still a highly resource-intensive activity, especially with the focus on validation and quality control checks at every step of the process. When critical decisions are to be made for the clinical development programme, time is of essence in reporting the analysis of clinical trial data and so is the accuracy of the results. Offshore delivery teams help meet these demands through access to a large talent pool and follow-the-sun model.

Whilst offering increasingly good infrastructure in emerging markets, BPOs, KPOs, SPOs and CROs can offer the niche skill sets (competent SAS programmers) and computational capabilities together with better cost structures. Within the scope of programming, high complexity work such as statistical programming (for efficacy analysis) is more challenging to deliver from an emerging geography than low complexity work related to database programming, safety reporting or data mapping. Selection of the outsourcing vendor cannot be done without thorough evaluation and deliberation and should be largely guided by the complexity of the tasks being outsourced. Regardless of the type of programming work that is outsourced, it is important to understand how it should be sustained and optimised in order to successfully achieve the desired objectives.



Sustaining and Optimising Statistical Programming Services in a Globally Distributed Model

a) Maintaining Steady State and a Balanced Mix of Onshore and Offshore Resources

An initial consideration for pharma companies when offshoring programming work is maintaining a balanced mix of in-house and onsite resources versus offshore resources. Getting these numbers right during each phase of outsourcing is crucial to ensure that there's enough in-house/onsite/onshore capacity available to provide mentoring and oversight as capability is being built within the offshore team, and while productivity of the offshore team is ramping up. Managing peaks and troughs both in the onshore and the offshore requirement is easier if contract resources are available at both locations. A good partner who can provide flex capacity offshore, instead of having only a captive team offshore, and having some contract resources onshore (in addition to a core in-house team) will address this need.

Alongside this, it is also crucial to consider the right kind of work to assign to the offshore group, and how it needs to change over time. Rather than allowing work to be sent through as it arrives, it is recommended that the work assigned to the offshore group is carefully planned so as to gradually increase the complexity of their work, to match with the gradual build of the capability. Ability and acceptance of the in-house and onshore teams to manage change should be continually monitored, especially with respect to change in the type of work they do, such as providing more oversight and taking on strategic responsibilities rather than being mostly focused on operational tasks.

b) Optimising Productivity

Productivity is a crucial element of ensuring a streamlined, effective and efficient working system and should not be overlooked when moving into new markets and working with international teams. There is a need to think beyond just ensuring the required levels of technical competence and functional expertise. Ensuring that desired levels of engagement and involvement within the offshore team are maintained, whether it's the captive group or a service provider, can make a real difference in this area. Having a sense of involvement and belonging will help improve their contribution and productivity. Various measures to achieve this, including onsite opportunities and involvement in end-to-end projects rather than discrete and isolated tasks spread across several projects, need to be considered.

In addition, it is important to communicate with the offshore team and take it into confidence in the event of change in strategy or significant organisational changes at the sponsor organisation. The frequency and mode of communication should be such that the distance and the remoteness can be overcome as much as possible – in-person interactions should also be used as required.

It is understandable that time zone differences can make constant communication, as well as other aspects of work, more challenging. However obvious it might seem, this should be top-of-the-mind at all times. The type of work assigned and the role on assigned projects has to factor in the time difference to ensure optimal productivity. If used efficiently and correctly, time difference can also be worked to advantage and can lead to enhanced productivity. The follow-the-sun model is a well-accepted model in today's globalised environment and has clearly yielded benefits for many businesses. The same applies to the programming and analysis aspects of clinical trials, especially



when there's a need to crunch the timelines for an interim analysis or for a regulatory submission.

c) Sustaining Productivity

Once optimal productivity has been achieved, sustaining these levels is at the top of the sponsor's and the service provider's priorities, especially in the competitive setting of an emerging market. In order to ensure that productivity remains optimised, it is essential to define, measure and track metrics to monitor the success of the engagement. With such evaluation procedures in place, along with mutually agreed targets, it is possible to gain a thorough understanding of the health of the engagement, and recognise any problems before they become urgent. While setting expectations and defining service level agreements (SLAs), it is critical to recognise that capability in the emerging markets has to be built over a period of time.

Another aspect of sustaining productivity levels is hiring and developing the right staff within the teams. The average staff profile in emerging markets is often different from what companies may be used to in developed markets with mature drug development services - this group may have unique needs for professional growth and development. A continued focus on training will ensure that all parties achieve the best possible results from the start.

Maintaining trained and productive workers in order to manage volume fluctuations and ensure speed and quality is also an area that needs attention. The demand-supply skew in the emerging markets cannot be ignored. A certain level of volume fluctuation and attrition has to be assumed and there should be a strategy (such as a ready pool or buffer resources) to mitigate any risk to the business.

Summary

Outsourcing clinical trial statistical programming and analysis has

clear and documented benefits to pharmaceutical companies. Employing an offshore strategy judiciously can improve availability of skilled resources, quality of analysis and adherence to timelines, ultimately helping companies make faster, more informed decisions at the right time. There are many factors to consider when outsourcing these services to new markets. While the emerging customer base and potential spending power is a huge incentive to those wishing to 'break' these markets, there are different factors and considerations which guide the decision to outsource programming and analysis services to key emerging markets such as China and India. In order to optimise and sustain delivery of such services from offshore, it is important to outsource to the right vendor and bring in teams, remotely and on the ground, that work well together in a cohesive and synergistic manner to achieve a company's objectives.

Bringing in external resources, and then managing them effectively, can be a complex process. This can be achieved by maintaining a balanced mix of resources, both onshore and offshore. The importance of optimising and sustaining productivity once these teams are in place cannot be underestimated. It is crucial for the customer and the vendor to work jointly towards such sustenance. Hence a spirit of true partnership and trust is a pre-requisite for success. This is not possible without the sponsor and the provider working hand-in-hand towards the common goal of continued success of the globally distributed model.

References

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