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Running a virtual department through outsourcing

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ABSTRACT

Ferring Pharmaceuticals' Global Biometrics department employs 20 people in the fields of Data Management, Statistical Programming and Biostatistics. The Department is based at Ferring's International PharmaScience Centre in Copenhagen.

Ferring is a successful research oriented midsize pharmaceutical company with several projects in development and in the pipeline. To cope with the increasing workload, strict regulations, ambitious timelines and high productivity, the Department increases its resources through a range of alliances with several external partners such as overseas and local CROs, EDC providers and independent consultants in combination with a high performance in-house team.

This paper discusses the main challenges of running a virtual department, building and maintaining successful partnerships and its value in contributing to achieve the main goal of reducing time to market.

INTRODUCTION

Ferring Pharmaceuticals is a privately owned pharmaceutical company.

The department of Global Biometrics was created following a restructuring of the company in 1999 and the creation of its International PharmaScience Centre (IPC) in Copenhagen. IPC is a state of the art purpose built R&D facilities with overall responsibility for the coordination of all Ferring's R&D work and conducts pharmaceutical development, non-clinical development, clinical development and regulatory affairs.

The Biometrics department consisted back in 1999 of nine fulltime employees from the fields of data management, statistical programming and biostatistics and was sufficient for coping with the existing workload mainly consisting of the finalisation of two phase III clinical trials. Along with company growth and new compounds entering clinical development the situation changed dramatically and even with the addition of a few more headcounts, adequately sourcing the new projects became an issue.

Currently, Global Biometrics has 19 employees and the workload amounts to 27 ongoing clinical trials from Phase I to Phase IV. Besides trial related tasks, other activities add to the workload e.g. responses to regulatory authorities, annual safety updates, e-submission preparations, to mention but a few.

To add to the complexity of the situation we have to comprehend that in the biometrics' area and in clinical development in general, workload is often difficult to predict; delays in patient recruitment are to be expected, regulatory requirements differ depending on the regions, projects might be discontinued due to the high attrition rates (the success rate for a drug entering clinical development to registration is approximately 11% across different therapeutic areas) are some of the characteristics of clinical development.

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From this perspective, it is easy to conclude that we need a sourcing model that is flexible i.e. adaptable to peaks and troughs, gives us access to first-rate capabilities and expertise, minimises risk and, given the resources available, allow us to focus on our core activities.

In the face of these challenges, Global Biometrics has developed a range of alliances with different partners and implemented different sourcing models.

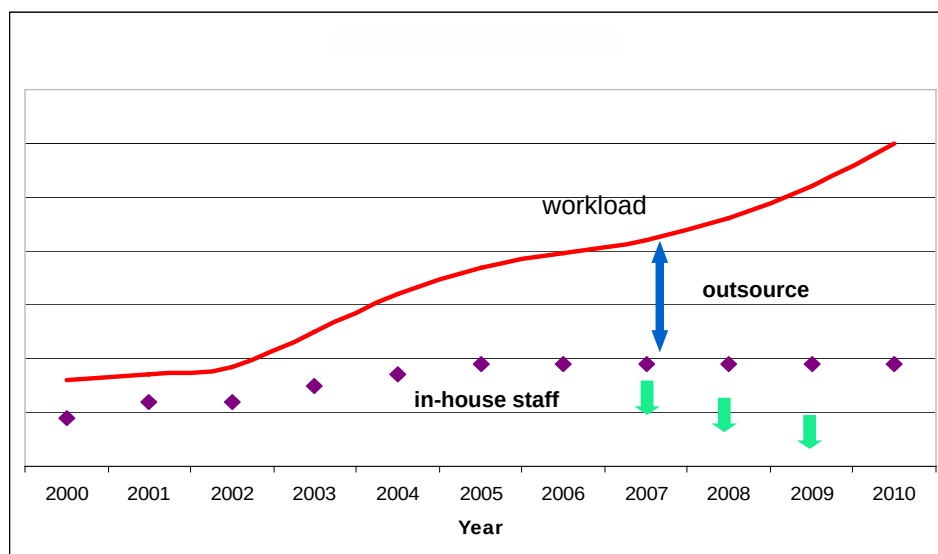
This paper discusses the sourcing models in place and the challenges of running a virtual department through outsourcing.

OUTSOURCING STRATEGY

Initially, the decision to outsource was based on tactical urgency; meaning that we decided what to outsource depending on what was required at the moment without having defined a clear policy as to which activities to outsource or to whom. It happened that we outsourced all biometrics activities – from protocol input to statistical report – to different CROs; this last decision depending mostly on availability.

Needless to say, this approach did not give the expected results; we were losing extremely valuable knowledge on our products and in-house time required to manage the outsourcing was unacceptable. Outsourcing costs in terms of in-house resources; and to minimise this cost is crucial, even more in a situation in which the number of in-house resources is staying flat.

Figure 1- The cost of outsourcing in terms of internal resources



In an internal survey from 2005, the main complaints were that vendors were not delivering according to expectations, poor communication and responsiveness and lack of pro-activeness. People on the other side of the fence (CROs) told another story complaining of one-sided negotiations, micro management, companies being held to higher standards than sponsors, little trust and sharing of information and not being considered part of the team (Avoca Group, 2005 survey).

By then we have realised that the approach should be a different one, one that required a strategic view to outsourcing i.e. defining what processes we want to outsource? Which model is the best one for us, for

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the specific tasks? What are the risks and how can we minimise them?

It was then when the decision to outsource all phase I trials was taken along with the decision to implement a preferred providers' policy and to focus on core i.e. our standards and therapeutic area / product specific knowledge.

Our goal is to manage workload delivering according to agreed timelines, with high quality deliverables according to – by us – specified standards. Basically, we expect seamlessness i.e. there should be no difference between the work done in-house to the one contracted out.

OUTSOURCING MODELS

Our first outsourcing experience was – as it is frequently the case – ad-hoc staff augmentation. Adding contractors in all of our areas of responsibility i.e. clinical data management, statistical programming and statistics – either independent or from small local providers – was the solution that was simplest to implement and posed the least risk.

This is probably the first model the majority of the companies put in place and the reasons why are various; in-house resources' time invested in communication, training and management is minimised, consultants are following the same procedures and working on the company systems and the principle of seamlessness is automatically achieved. These characteristics make this, one of the most effective models.

Staff augmentation through local providers gave us the possibility to cover immediate business needs and it has also proved to be a good model in the long-term perspective as well, because until today – some nine years after we commenced to outsource – we have access to a pool of resources that are familiar with our systems and procedures thus minimising “time to full production” capability.

Along with increasing workload, the former “peaks” became a new baseline and given the small size of local CROs we had to start looking elsewhere. This resulted in some overseas consultants from south-east Asia in-sourced in our teams in Copenhagen, for periods ranging from 6 months to 2 years in order to augment the work force on a medium term basis.

Such experience gained during these years of intensive outsourcing, allowed us to take a new step in the outsourcing ladder, namely, the establishment of an off-shoring facility in India. We believe that this is a natural step in the extension of the “staff augmentation” model since the consultants that have been working at our premises for a period of one to two years will be the liaison and bridging element to the off-shore office.

The off-shore group will be working according to our procedures, logging into our systems, sharing the same environment. This offers a clear advantage compared to the project outsourcing model i.e. the final control of deliveries is not longer necessary since working on the same project allows interaction and detection of any problems early on. Another major advantage of this model is the offshore partner taking responsibility for some time consuming and fundamental activities such as day to day management, recruitment, training and personnel issues.

In the year 2001 we introduced electronic data capture (EDC) for all new studies from phase II – IV and the technology is now migrating into phase I trials. It was at this juncture, we initiated what would be our second major outsourcing model, namely, “out-tasking”. Setting up eCRF applications and software development is not our core business and our limited resources do not justify a technology transfer model.

Although we continued to keep data management activities in-house, supported by local contractors, the increasing number of trials made it necessary to outsource data management tasks as well. The collaboration with our EDC vendor has been ongoing for nine years and given the nature of the task, it made them the first-choice partner for managing data management for the studies we could not keep in-

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house.

In parallel with these models, Global Biometrics also outsources entire projects e.g. all biometric tasks for phase I trials. Generally, phase I trials are of short duration, resource intensive and therefore, keeping them in-house was never an option. Phase I trials are not the only studies we outsource in their entirety; we also outsource other trials or even a group of trials e.g. the whole phase III B program for one of our compounds to external CROs. It does happen that we also outsource parts of the work to CROs e.g. creation of analysis data sets, creation of tables, listings and figures, etc.

In order to minimise the amount of in-house resources needed for training and management, we have chosen two preferred providers, one in Europe – a small CRO – and one in the US – a specialised CRO – that offers both scalability and excellent know-how.

With all these solutions in place, we have achieved great flexibility and deciding which model to use will depend on the project characteristics. Whereas any type of model would work for well defined- and described small projects e.g. a set of tables, experience indicates that this is not the case for medium and large standalone or integrated projects.

Phase I studies are a good example of standalone projects that are successfully outsourced to our preferred providers. Like any other project, they require effective and proactive project management that can be provided by the right CRO. Along with repeated business, the role of the project manager becomes fundamental since it is the one guaranteeing information- and knowledge sharing.

For standalone projects as the ones described above, the CRO uses its own procedures and systems e.g. own data management systems, programming environment, etc delivering the end product according to our specifications.

Although this model works well in the previous case, it is definitely more challenging whenever we outsource more complex, integrated projects that depend upon projects done in-house e.g. the outsourcing of a phase III B program. In cases such as this one, in which we need to ensure that our specific and detailed knowledge on the project is shared, that standards are followed to facilitate data integration and consequently, the interaction between in-house and external partner is very intensive, the offshore solution – in our setup - seems to be more appropriate. The reason for this being that working according to the same SOPs, sharing the same systems will facilitate the process significantly.

For the sake of illustration, our approach when outsourcing phase I studies is given below.

Outsourcing of Phase I studies put into practise

Contract aspects

One of the keys to successful relationships is setting clear expectations for the scope of work. For this purpose Biometrics' standard bid grid is made part of the contract. This document defines in detail each task and deliverable associated with the study including a specification of responsibility, timelines and related Ferring SOPs where applicable. Upon receipt of the proposal a meeting with the CRO is scheduled to ensure mutual understanding of responsibilities and assumptions.

Project Management (PM)

In addition to the typical Biometrics functions i.e. data management, statistics and statistical programming a Project Manager is appointed by the CRO as a main point of contact during the project. This person works jointly with the Biometrics PM to ensure the success of the project.

Communication Plan

Who wants to know what, when and how is defined in a communication plan prepared by the CRO and Biometrics PMs.

Kick-off Meeting

A kick-off meeting with all team members from the CRO and Ferring serves as a starting point for the study team collaboration with the purpose of establishing roles and responsibilities, clarifying expectations and gaining a common understanding of the process and timelines. The meeting is preferably conducted face to face.

Day-to-day tasks throughout the study life cycle

During the course of the study the team members of the CRO are expected to communicate directly with the study sites, other service providers such as laboratories and functions within Biometrics at the CRO and Ferring. A great amount of e-mails and telephone contacts on a daily basis are not recommended. Structured communication is necessary to allow time for doing the actual work. To achieve a productive work environment for the team members the CRO PM must support the study team by assuming a proactive role instead of waiting for the problems and issues to occur. If problems do arise, the CRO PM should involve the sponsor PM immediately to discuss possible impact on timelines and to agree on a solution to the problem.

Regularly scheduled study status meetings are important for follow-up of timelines and for getting a better understanding of study progress and team members needs. Depending on the issues at hand participation by all team members is not necessary every time. A detailed scheme for managing performance by tracking tasks and deliverables based on predefined completion metrics is updated at the meetings and forwarded to all team members after the meetings.

When it comes to the deliverables for the study, e.g. the Data Management Plan, study database or SAP, it's acknowledged that final responsibility of deliverables lies with the sponsor. However, the CRO is expected to apply quality checks of the documents and files in-house before sending them to Ferring to minimize the time needed for review.

Evaluation and feedback

At study completion an evaluation of the services provided by the CRO is performed and feedback is given to the CRO.

The evaluation may lead to:

- identification of new ideas and experiences
- avoidance of repeating mistakes
- finding areas where training is needed
- quality or method improvement

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KEY SUCCESS FACTORS

Moving from tactical urgency to strategic outsourcing meant moving from a rather erratic policy characterised by the choice of several outsourcing partners towards a consistent approach, building long-term relationships with preferred providers.

The main driver behind the change was that the first approach required an unjustifiable investment of in-house resources to manage the outsourcing and control deliverables that were seldom according to our expectations to start with. This created a sense of insecurity and frustration among internal staff that led to micro management and increased mistrust in both camps. Adding to the investment of in-house resources for the control of deliverables, the investment in repeated training for every new vendor added to the total cost.

The identifiable key issue here is that we outsource because we do not have internal resources and thus we cannot spend the already strained in-house resources in controlling or redoing work we have already paid for. Therefore, establishing long-term relationships with preferred providers, based in mutual trust and relationship building is the key success factor.

The choice of the preferred provider is a key aspect that requires thorough consideration. Although many companies feel more comfortable and feel safer choosing established CROs, we have chosen mid-sized companies paying careful attention to the cultural match; to be able to successfully build trustful and long-term relationships require good communication and shared values.

CHALLENGES AND TOOLS

Working in a virtual environment in combination with a workforce across different countries and cultures add to the complexity of the matter at hand. It is important to have what might be described as cultural awareness, i.e. an understanding of the differences between the specific practises involved in order to avoid miscommunication. To take this into practice, the department and consultants participated in a two-day workshop on cultural awareness in which several aspects were highlighted e.g. communication styles and e-mail culture, to name a few.

Building long-term relationships require stability, good communication tools and unambiguous clarification of expectations.

In terms of stability, the best scenario is to be able to work with the same teams over time. This is though not always achievable and therefore, a strategy for knowledge transfer should be in place.

Even when teams are scattered over a wide spread geographical region and across different cultures, it is fundamental to feel they are part of the same team and working toward the same goals. Therefore, meetings face-to-face, organising periods in which off-shore consultants come and work with the sponsor's team, frequent video-calls are part of the tools that have to be in place.

Along with the appropriate tools, clarification of expectations is one key factor in all kind of relationship. Clear specification of deliverables is fundamental and training on the customer's processes and standard operating procedures – in the cases it applies – can really make a difference.

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CONCLUSION

It requires work and insight to make outsourcing work successfully but it is possible. Building successful partnerships require trust, openness and communication, supported by adequate tools.

Successful teams – virtual or not – require common goals and commitment and this can only be achieved in an environment of trust and respect, in which clear leadership and avoidance of micro-management are important aspects.

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