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Global Outsourcing and Vendor Management: Key Influence Factors and Strategies

Few would argue that global outsourcing is accelerating at an increasingly rapid pace. But what does outsourcing really mean to business, and what is it worth?

By far the fastest growing area of R&D spending is outsourcing. Exceeding $60 billion in 2016, sponsor company spending on contract R&D services is growing at six times the annual rate of spending on internal staff, infrastructure, and technology support. Clearly, pharmaceutical and biotechnology reliance on outsourcing is high and increasing. Sponsor companies have continued their push to lower their operating costs while leveraging expertise to help manage growth in drug development pipelines.

In the pharmaceutical industry, about one-third of all drugs in the pipeline of the top ten pharmaceutical companies were initially developed elsewhere. Astra Zeneca, for instance, has been in the process of moving its global headquarters to Cambridge to harness the university's scientific knowledge. Pfizer has undertaken a similar strategy in the United Sates, having positioned many of its research and development facilities close to major bioscience hubs. Bristol-Myers-Squibb has collaborated with Allied Minds, a Boston-based group on commercialisation of academic research to scour American universities for innovative drug discovery ideas, and GlaxoSmithKline has recently teamed up with the University of Leicester to develop novel drugs against blood cancer, showing that the outsourcing trend is an international phenomenon.

Why do companies outsource?

- Pharmaceutical companies are increasingly outsourcing different activities to vendors as a strategy to stay competitive and flexible in a world of exponentially growing knowledge, new technologies and an unstable economic environment. Globally, the pharmaceutical industry is facing strong pressure to contain costs and therefore the expense is largely being directed towards outsourcing.

- Because of frequent interaction between sponsor and vendors, the topic of vendor oversight is in the centre of attention. Because of the outsourcing strategies employed, the question arises if vendors are doing what they were hired to do and if they are adhering to the quality necessary. With the growing use of contract research organisations (CROs) and other vendors, leaders in the field raise their concerns about increasing speed on pharmaceutical matters, like the increasing complexity of clinical trials, rapid recruitment of patients, or finding the best vendors or investigators for one's own trial, and quality, while trying to adapt the vendor oversight processes per International Council for Harmonisation (ICH) Good Clinical Practice (GCP) E6 (R2) guidelines.

- Companies use outsourcing to enter the market to avoid delays in hiring and infrastructure development, as well as to prevent internal resistance to new ideas. A pressing question for pharmaceutical companies is how best to organise the R&D activities to improve productivity and flexibility: which activities to keep in-house and which to outsource to CROs? Processes that are usually outsourced include medical writing, submission planning and publishing, regulatory data and information management, local regulatory affairs, pharmaceutical-chemical writing, labelling, agency liaison, regulatory strategy, translation, administrative documents, dossier conversion, and literature searches, etc. The regulatory affairs functions most likely to be outsourced include labelling, electronic core technical document (eCTD) assembly, training and submission tracking, indexing, and archival.

- In practice, this means that a CRO can provide quick assistance in a task that is urgent and can be outsourced, or that would otherwise burden the company's personnel. Anyway, getting ideas and expertise from external sources is a well-established practice.

There is always the possibility that the cooperation does not work. Even so, switching CROs is also expensive. The outsourcing policy may change in a way that the company back-sources the regulatory affairs tasks in-house. To obtain the most success out of the vendor management process, a strategic approach is required – to build and maintain the relationships with the best and preferred vendors. Good suppliers, with which a trustworthy and thriving collaboration is possible, are hard to get. Therefore, it is important to nurture the relationship between sponsor, and vendors the sponsor does not want to lose.

The following practices help maintain a strong sponsor-vendor relationship:

- *Share information and priorities:* To support the vendors to effectively meet the sponsor's need, it is crucial to share the

- sponsor's information and priorities. This means providing the necessary information in a timely manner, including launch dates, changes in the trial design, forecast information, and other relevant information that might affect the quality or service of the outsourced activity.
- *Allow strategy and innovation:* The sponsor and vendor should work together on a strategy. By following this, the sponsor will receive the best value for the invested money, as this kind of collaboration is for sure the most effective one. The vendor is an expert in the outsourced area and can therefore provide valuable insight or innovative suggestions that could improve the service or would even provide cost savings, resulting in a competitive advantage. Hence, the vendor should be invited to meetings that involve the service the vendor is working for. It is a double-sided collaboration and not a oneway business relationship.
- *Focus on the long-term plans:* Short-term relationships with vendors are not recommended as they will only lead to shortterm gains and hence to minor cost savings. The real value will result from long-term partnership, which will enable trust and engagement from the contracted vendors. Consequently, this will result in discounts, preferable treatment and access to expert knowledge.
- *Focus on win-win agreements:* Appreciative and trustworthy business relationships cannot be established through overruling negotiation strategies. Quite the contrary, this will cause resentment that could lead to further problems, and unproductive discussions. Instead, negotiations of agreements should be focused, and allow both parties to experience a good feeling about the agreement.

Recent revisions outlined in ICH E6 (R2) have provided an impetus for sponsors to reevaluate their oversight and quality management processes throughout the clinical development process. Specifically, ICH recommends that a sponsor maintain oversight of "any trial-related duties and functions carried out on its behalf, including trial-related duties and functions that are subcontracted to another party by the sponsor's contracted CRO(s)." Identifying, qualifying, and selecting clinical providers are early and critical steps in the clinical outsourcing process that require attention.

Among the different non-clinical activities, logistics and procurement are of great importance as they represent a large portion of healthcare organisations' expenditure and are essential for their operational performance. Procurement and logistics outsourcing have been considered useful to simplify the procedures for finalising contracts, to encourage competition between supplying firms through transparent selection practices, and to improve the efficiency and effectiveness of the entire healthcare system by increasing economies of scale and scope.

Studying the clinical trials outsourced within each therapeutic area globally, oncology was the area that topped the list across all geographies. The other areas were ranked in order of their importance in those relevant regions. Other diseases such as ophthalmology, speciality disorders, orphan diseases and neurology also received substantial interest, but did not find their spot within the top five areas.

As the COVID-19 pandemic continues to unfold, the capabilities of supply chains are coming into sharp focus, not so much in terms of cost-efficiency, but on their ability to be resilient and effective in delivery. This is why understanding the potential implications of complex outsourcing in the healthcare sector is of paramount importance.

Additionally, pharmaceuticals face increasingly stringent regulatory scrutiny around third-party relationship management and seek to bolster their vendor management capabilities to ensure compliance with industry standards.

The outsourcing processes consist of a sequence of stages, summarised as follows:

- The early build-up stage, in which potential providers are selected to negotiate and develop a (formal or informal) contract for the provision of logistics and procurement services.
- The execution stage, in which the commitments and rules of action agreed upon by the parties in the previous stage are carried into effect; in this phase, operations are organised, executed, coordinated and monitored, entailing adaptations and increased experience between the companies of the respective activities.
- A long-term stage, in which routine approaches are institutionalised and several kinds of bonds between the parties arise or strengthen because of extensive formal and informal adaptations. These bonds have an important function in favouring the creation of longterm relationships and can relate to the technologies used and shared by the parties, personal knowledge and trust, administrative routines, procedures and legal contracts.

A Glance at the Preclinical Outsourcing Market:

Frost & Sullivan valued the global CRO market at $28.75 billion in 2014. Approximately 13.1% of the total share arises from the preclinical segment. Globally, in recent years, preclinical outsourcing had experienced a surge in growth rate, leading to capacity constraints. Companies have made large investments in expanding capacities. Capacity issues are likely to result in declining growth over the longterm forecast period. One of the leading areas within the preclinical outsourcing market is preclinical toxicology. Earlier, preclinical outsourcing was predominantly conducted in-house by pharma companies, but it has been observed that sponsors are becoming more open to the idea of outsourcing more of these services to CROs to reduce the price burden. The majority of the revenues for this segment arise from North America, followed by Europe, Asia-Pacific, and the rest of the world.

Defining the Required Benefits

The first step to realising the desired benefits is a clear definition of end objectives and expectations. The main challenge is to operate efficiently while balancing priorities to innovate and stay relevant in the market. These challenges can be managed through proactive and transparent service level agreements (SLAs), performance metrics, and continuous operational improvements.

A quality vendor performance assesses how the vendor is performing against key performance indicators (KPIs) established in the vendor's contract. Performance reviews aim to monitor compliance of contractually agreed upon KPIs, identify areas where the vendor is not performing to expectations, partner with the vendor to resolve low vendor performance, benchmark the vendor's performance against similar vendors, and assess performance trends. Each performance review should have a scoring model that quantifies the performance level. Once the internal review is complete, the vendor management office (VMO – a business unit within the enterprise that is responsible for evaluating suppliers of goods and services, and overseeing regular interaction and long-term relationships with vendors) should work with the vendor to work through any low scores. The best way to resolve low scores is to have the vendor create an action plan and collaborate with the vendor to track the vendor's progress to resolution with SMART goals, to ensure both parties obtain the desired results. SMART goals are specific, measurable, attainable, relevant, and time-bound objectives.

Tracking the Realised Benefits:
Post-contract signature issues, along with lack of innovation and leading practices, are two of the top five challenges companies face with their outsourced vendors. With a lack of clear definition on how to track innovation benefits, it is challenging to differentiate the value derived due to innovation. The industry still struggles when it comes to measuring quality; therefore, it becomes increasingly more important to investigate how the performance of the contracted vendors can be measured. Effective clinical trial management and improvement can only happen if there are valid and reliable quality metrics. Metrics should have standard definitions of key terms and study milestones to ensure that the metrics are measuring the right factors in the right way. Driven by competitive and regulatory pressures, the purpose is to be proactive on understanding the level of risk, so that it is possible to measure and monitor risks over the course of the trial.

Motivating the Vendor to Perform:
Motivation is key to forward momentum. The vendor's employees play a key role in effective delivery and keeping them motivated is a decisive success factor of a well-functioning service delivery model.

Vendor Management Operating Model
To better harness and manage innovation, companies likely need flexible vendor management operating models that act as strategic enablers of innovation. This means that the processes, while well-defined, should be well-differentiated and able to change quickly to adapt to evolving business needs. It also means having the appropriate governance in place.

In some cases, it makes sense for a third party to perform select functions that are non-core to the organisation so that the sponsor can adapt a more flexible operating model.

Vendor Management Tools
Identifying tools that can help automate operations, especially while performing such repetitive tasks as performance reporting and contract analytics, is important. Tool adoption surely helps to streamline processes. Close collaboration with service providers to develop and customise tools is an effective way to meet the innovation needs of the organisation.

- Identifying competency sets from model and list, with development options.
- Strategic reviews of capabilities required and weighting of priorities.
- Tailored training workshops on vendor management to build individual competencies.
- Facilitated events to develop collective team capabilities.
- Webinars and videoconferences on selected competency areas.

Vendor Management Skill Sets
Not all projects are the same, not all companies are the same, and not all vendor relationships are the same. There is not one universal skill-set to be an effective vendor manager. Many factors determine what competencies (or capabilities) are needed. These are ten typical factors more influential in determining what competencies are needed, in what priority, and to what depth.

1. Lifecycle responsibility – whole process or one phase (mostly delivery).
2. Relationship with vendor – transactional or partnering (collaborative).
3. Project or programme – deliverables and milestones, or service levels and quality.
4. Extent of integration into client business.
5. Balance of expertise – client or vendor side.
6. New or ongoing project/programme – kick-off vs. maintain.
7. Project complexity, size, budget, depth.
8. Location of vendor.
9. Governance requirements, structure and process.
10. Level of responsibility, discretion and accountability of vendor manager.

Contractual Constructs:
Although cost savings and service quality improvement appear to be the overriding motivations for outsourcing from public to private sector, the success of outsourcing also depends on a number of different factors. In fact, hidden costs of outsourcing

occur in selection, managing the relationship between supplier and outsourcer, and making changes to the service contract, all of which can offset any cost savings and quality improvements identified at the start of the outsourcing contract.

The development of clear risk assessment guidelines and SLA review guidelines can minimise contract renegotiation and associated changes during contract execution. Custom, value-driven, and gain-share pricing models are appropriate for select initiatives and service providers. A move toward these custom models can help facilitate innovation, but they also require an increased focus on financial management.

A Look Ahead

Through working with many different vendors, where different processes are outsourced, vendor management of third parties should not just be essential to gain an oversight over the contracted vendors but should also maintain a mutually beneficial relationship. Beyond the lowered cost, the main value added is the achievement of benefits provided by a vendor that would normally not be delivered by other customers.

A great challenge for vendor managers is to compete with other sponsors or companies to attract and maintain the best vendors and their performances. Today, vendors indeed still compete with other vendors, but sponsors do also have to compete with other sponsors for the best vendors in their fields. In these times, it is highly important for the sponsor to be aware that a positive sponsor-vendor relationship and providing critical feedback is essential for the daily business with the contracted vendors. If there is a good relationship between the sponsor and the vendor, it is more likely for sponsors to rely on vendors, as the motivation to support one another in a good relationship.

Since the scale, complexity and costs of clinical trials have increased during the years, the requirement for risk-based quality systems have emerged. As risk management is essential to identify and avoid potential costs and performances or technical risks to a process or a system, it is mandatory to understand how to introduce, implement and apply risk management principles to clinical trials. For risk management in the GCP environment, no detailed guidelines or regulations are applicable that define how the processes of risk management should be incorporated. Here the risk process is divided into risk identification and assessment, risk treatment, review of risks and the risk communication and documentation which has to be performed for the whole process. About quality methods, it is necessary to define the key methods for proper quality management, as well as the risk management tools for maintaining a well-functioning quality system, which is needed for ongoing management of vendors. Finding ways to manage quality efficiently is one of the central issues faced by clinical development teams. The quality methods consist of quality control and quality assurance. Quality control is defined by monitoring the sites, which can be on-site monitoring or centralised monitoring. With recent regulatory guidance, risk-based monitoring with a mix of both types is becoming the industry's actual approach to clinical monitoring. An audit belongs to the quality assurance activity and is a systematic and independent examination of trial-related activities. For risk management tools, the ICH Q9 guideline mentions many useful tools, but the base for the quality risk management tools is covered through the root cause analysis and the risk analysis, as these are the two easiest handling tools.

Early-stage clinical trial services such as bioanalytics will witness a major boost in coming years, due to their increasing role in eliminating unpromising drug candidates at an early stage, thereby saving R&D cost. Demand for functional services, such as data management, consulting, logistics, translation, regulatory and consulting, is also experiencing strong growth. The co-drug development model will be the future of the drugdevelopment industry, wherein CRO companies will join hands with pharmaceutical companies to develop a drug. As personalised medicine emerges, the co-development of a drug and the diagnostic marker will go hand in hand. This will compel the CROs to collaborate with pharmaceutical and diagnostic companies in the future.

The eClinical trial solution is gaining popularity. It helps in reducing the time and cost of clinical trials, and in streamlining the regulatory process and audit trials for faster approval. Additionally, since there is also an immense need for real-time, evidence-based data, this has paved the way for eClinical technologies that will play a vital role in the way data is being managed in these CROs.

Market Watch

The current focus strategy has centred on the concept of bigger equals better; companies are gearing up to broaden the breadth of services offered. With personalised medicine becoming a focus, central laboratory testing will also add value to a CRO. One of the recent M&A deals is the acquisition of Covance by LabCorp for $5.6 billion. Covance is a CRO with annual revenue of $2.5 billion, with about 12500 employees in over 60 countries, and stands second after Quintiles, which had annual revenue of $3.8 billion in 2013. LabCorp is a diagnostic reference laboratory with annual revenue of $5.8 billion in 2013, with over 34,000 employees worldwide. The combined revenue of both LabCorp and Covance is aligned to make LabCorp a market leader and number one in the clinical laboratory market. Global expansion continues to remain the area of priority for many CROs today.

In terms of annual revenue and market share, this strategic long-term alliance is aligned to beat the market leaders. The combination of safety and efficacy data for drug approval from Covance and diagnostic data from 75 million patients from LabCorp will be an effective way to a more costeffective approach toward improving patient diagnostics and also advancing personalised medicine. Clients will be able to see more value for their products.

Covance generates more safety and efficacy data for the approval of innovative medicines than any other company in the world, and LabCorp has longitudinal diagnostic data from more than 75 million patients. This combination leads the way to more costeffective healthcare by improving the safety and efficacy of drug therapies, enabling accurate patient diagnostics and advancing evidence-based medicines, which will enable their clients to demonstrate the value of their products and services to patients and payers. As a result, there will be greater opportunities for both companies because they will now have a broader universe to compete.

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