

# Outsourcing pharmacovigilance

**The impact of pharmacovigilance on the safety and protection of patients is being recognised increasingly by regulatory authorities worldwide. Legislation now stipulates the need for absolute transparency in monitoring and reporting on the safety profile of a medicine. To comply with these demands, pharmaceutical companies must manage and document data comprehensively throughout a drug's entire life cycle before and after launch.**

**In line with these requirements, growing numbers of companies are recognising that a more effective approach to pharmacovigilance management and safety data evaluation is essential to protect patients, products and ultimately the company itself.**

When implemented in-house, pharmacovigilance activity can often present a significant cost and time burden for companies. In contrast, a recent study of pharmacovigilance deployments has shown that substantial cost savings, of 30-40 per cent, can be achieved through outsourced pharmacovigilance activity. By outsourcing to a specialist provider, companies are able to reduce fixed overhead costs, avoid high upfront investments, secure additional capacity and increase resource flexibility.

## EXTERNAL INFLUENCES

To ensure an effective pharmacovigilance function, it is imperative that the correct tools are used to detect and respond to any safety concerns. Standard operating procedures (SOPs) that meet regulatory obligations must be put in place to guarantee quality measures for recording, reporting and managing adverse events (AEs). Systems must also be implemented for receiving both spontaneous reports and clinical trial reports and forwarding these to the appropriate bodies and individuals.

***“A quantitative methodology... should be combined with expert judgement to define the safety profile of a drug”***

Sponsors must ensure that systems are in place to enable them to manage the overall safety assessment process transparently. Processes should be implemented to check that arrangements for projects have been established and documented correctly, and that procedures are being adhered to. It is also essential that a quantitative methodology is not used in isolation: it should be combined with expert judgement to define the safety profile of a drug.

## SPECIALIST SERVICE PROVIDERS

To comply with the strict reporting requirements, many companies have increased the number of qualified staff they employ, but now face shrinking budgets. These companies have been reluctant to outsource their drug safety activities due to fears about losing control of processes and proprietary

knowledge, as well as concerns surrounding the legal ramifications if the outsourcing partner 'gets it wrong'.

Today's marketplace offers a broad choice of both service providers and scope of pharmacovigilance services and, in the face of rising profit pressures, many companies are increasingly turning to specialist providers as a way to gain access to innovative ideas and reduce expenses. Manufacturers can benefit from specific support not available in-house through flexible cover at times of high work throughput, while saving on recurring personnel and infrastructure costs.

The functions that can be outsourced include the review of safety results from preclinical and clinical studies, expedited reporting to regulatory authorities, literature screening for safety issues and case reports, surveillance of emerging data and the evaluation of benefit and risk for a product. The preparation of development risk management plans, SOPs, system evaluation, database evaluation and validation, as well as labelling evaluation can also be outsourced.

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Evaluation of individual serious cases and AEs of special interest leads to the need to address any safety issues identified. In turn, the periodic cumulative assessment of all available clinical data must be performed; this aggregate review depends on competent reviewers and auditable documentation. A specialist provider will have the capabilities to provide ongoing expert physician review to ensure the highest levels of safety. Such companies will be able to develop a full understanding of a drug's safety profile and advise whether or not any issues arising during a study could have an impact on its potential safety profile.

### **ADVANTAGES OF OUTSOURCING**

Outsourcing allows companies to benefit from a range of customised services. A provider with proven expertise can plan and execute strategies that match a pharmaceutical company's specifications, personnel and technology. As a result, the company can benefit from increased speed and flexibility that provide access to a virtual team and allow particular individuals to be brought in when specific expertise is required. In addition, outsourcing to the right company provides access to experienced pharmacovigilance physicians who have a critical scientific eye, as well as a broad view of the industry.

Additionally, service providers can greatly improve the efficiency of ingrained habits and processes by offering a short-cut to radical improvements in efficiency, cost and speed. This allows outsourcers to implement new and better methods and means that, to an extent, they can rely on another firm's infrastructure rather than providing the capital themselves. In addition, outsourcing non-core and transactional tasks can enable a company to focus on its fundamental competencies.

The ability to pass on the responsibility of unblinding to the provider is an additional potential benefit of outsourcing safety evaluations during clinical development. This enables more rigorous control and management of who is aware of patient treatment assignments for reported suspected unexpected serious adverse reactions (SUSARs). →

➔ Manufacturers must remember that successful outsourcing will call for monitoring of progress, performing inspections for quality data assurance, evaluating problems and proposing corrections, as well as preparing plans for terminating the outsourced services. However, outsourcing should be approached with caution in order to manage risks and maximise success. There are a number of practices that will help manufacturers choose the right partner.

To ensure a successful and efficient relationship between the pharmaceutical company, the contract research organisation and the pharmacovigilance service provider, it is essential that collaborative processes are established that will not threaten the future of a drug. A sponsor action plan should be designed at the beginning of any development programme, setting out predetermined objectives and measures to evaluate the outsourcing solutions. Legal, training and confidentiality requirements must also be developed at this point.

Various outsourcing options are available, ranging from individual contractors and pharmacovigilance consultants to specialist pharmacovigilance consultancies. The outsourcing process is often divided between multiple providers, meaning that the safety provider is not always in direct contact with the primary sponsor. In this instance, it is important to ensure that the conduct of safety management in a clinical trial is a collaborative process requiring co-operation in evolving and implementing activities.

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A detailed contractual arrangement should be put in place that clearly describes the roles and responsibilities of each party for all aspects of pharmacovigilance outsourcing. Further to this, the continuous exchange of information between the provider and the sponsor is another key element to success. However, sponsors must be certain that this is transferred safely and confidentiality agreements are not compromised. It is vital for sponsors to check thoroughly the competency of the provider they choose. A good starting point is to undertake an SOP audit alongside investigating the provider’s team competencies and experience.

### **SAFETY SIGNAL IDENTIFICATION**

Another important consideration is the detection of safety signals and the guarantee that signal identification is not lost due to segmentation of the analysis different parties. Also, responsibility for safety review meetings, data analyses, searches, compilation of documentation and the ongoing creation of risk management plans needs to be defined prior to outsourcing to avoid misunderstandings. If this responsibility lies with the sponsor, it is imperative that the provider is aware of any new information or issues and can perform its work in line with the updated safety profile of the drug.

Working with a specialised provider that is able to contribute expert advice and medical liaison will enable these challenges to be routinely addressed. As a result, pharmaceutical companies can be assured that the clinical experience gained in clinical trials will contribute to building the safety profile of a drug, rather than unnecessarily

being the reason for bringing its development to a halt.

Outsourcing pharmacovigilance management to a specialist provider can provide cost savings, access to expertise, process improvements and the avoidance of fixed costs. While the advantages of outsourcing are apparent, it is vital that pharmaceutical and biotechnology organisations ensure they remain in command, orchestrating the activities of different providers and guaranteeing that information is continuously provided and exchanged safely between the contributors. Early investment in an efficient pharmacovigilance system will maximise the chance of a drug progressing to market and avoid potentially expensive and damaging safety crises.



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## **Executive summary**

- The outsourcing model is increasingly being recognised by pharmaceutical companies as a solution to manage their processes and contend with pressure on profitability and a rising demand for efficiency
- By outsourcing pharmacovigilance activity, a company can reduce fixed overhead costs and avoid high upfront investments, while securing additional resource capacity and flexibility
- Pharmaceutical companies can benefit from increased speed and flexibility while being provided with access to a virtual team that allows particular individuals to be brought in when specific expertise is required
- To ensure a successful and efficient relationship between the pharmaceutical company and the pharmacovigilance service provider, it is essential that collaborative processes are established.
- It is vital that pharmaceutical and biotechnology organisations ensure they remain in command, orchestrating the activities of different providers
- Early investment in an efficient pharmacovigilance system will maximise the chance of a drug progressing to market.