

Outsourcing Trends in Pharmacovigilance

Drug safety has moved into the media spotlight and now more than ever it is essential that patient safety is seen to be of utmost importance to regulators as well as pharmaceutical companies. Outsourcing in the pharmaceutical market has grown vastly over the last 10 years, with PV market estimated to reach \$5billion in 2019, at a Compound Annual Growth Rate (CAGR) of 12.9% from 2013 to 2019. It has become almost standard practice among multinational companies to develop global sourcing programs. The outsourcing of pharmacovigilance tasks provides a flexible solution to the ever changing demands of running a specialist pharmacovigilance team. Duties usually be performed in-house are contracted to a dedicated service provider, whether it is on a full service, partial or project basis. The trend seen in drug safety services has largely paralleled the trends seen in the clinical research and product development services.

When Outsourcing helps?

- When we need to have short term additional resources.
- When we need to have readymade troop of skilled and trained resources.
- When we need the flexibility to respond to varying workloads.
- Outsourcing approach of 'pay as you go' allows you to respond fully to regulatory obligations, without the need of retaining a full pharmacovigilance team on the payroll.
- The benefits of outsourcing include reduced costs due to less effort needed for staff recruitment, management and training. With stricter regulatory requirements, the hiring of experienced safety personnel has become highly competitive.

What services can be outsourced?

Company size, the size of the pharmacovigilance department and existing license or development partnerships influence outsourcing decisions. It is possible to outsource an entire pharmacovigilance (end to end) or medical information department or just individual elements, depending on your requirements.

Recent Trends?

The range of contracted services is determined by the type of safety service providers, including individual consultants, specialty Clinical Research Organizations (CROs), large, full-service CROs and global service providers under the umbrella of business process outsourcing (BPO). Life science companies, CRO's, KPO's, and BPO's shifted for doing this business. These companies come up with robust technology and mature processes to effectively address risks and concerns associated with delegating responsibility to service providers. The negotiations between the pharmaceutical company and the regulatory authorities on the risk management program had been unsuccessful over several years so the pressure has increased of late, in order to comply with evolving regulations

worldwide. Regulatory observation along the entire product life cycle has seen a substantial increase, with all areas of the business being affected.

Examples of outsourcing consultation trends include:

- Full PV service outsourcing (ICSR management & reporting of cases).
 - a. Small biotech companies typically have no drug safety department and routinely Outsource all safety services including the safety database.
 - b. Mid-sized pharma companies generally have the knowledge and resources to cater to the demands of the global pharmacovigilance environment. They face challenges to meet fluctuating resource needs associated with a changing product development.
 - c. Large pharma companies have comprehensive expert pharmacovigilance Departments with global infrastructure and databases.
- Case processing (Regulators requested an active surveillance study to detect rare and serious adverse events for risk minimization).
- Literature screening (Usually provide flexible end-to-end literature search and review solutions that assist companies and individuals to meet their regulatory goals).
 - a. Literature review help users to stay updated in their research.
 - b. Provides complete picture of today's global clinical research in clinical medicine which is enabled by broad coverage with numerous access point, extensive search capabilities and coverage of immense data.
 - c. Save research time by providing one source for variety of research data including abstracts, author's name, contact details and information per bibliographic record than in other resources.
- Signal detection/ benefits risk assessment (Contracted experts are external, they can provide an unbiased view, may have special value in decision making process involved in signal detection and risk management activities required for the drug).
- Safety services require availability of sufficient talent with significant expertise (e.g., writing periodic safety update reports and performing signal identification and analysis, running patient registries as part of Risk Management Plans).
- Staff that already has product expertise and familiarity with issues such as product recalls and accurate coding of commonly reported events can implement and assess better risk management activities.
- Pharmacovigilance requires informed decisions regarding the safety and risk of the product, while meeting targets of quality, time, and cost. Individual cases are processed, events are coded consistently and accurately to provide very clean line listings after data lock for aggregate reports. This saves time and effort typically spent on data clean up.
- Effective monitoring may include the aggregate reporting team working with and sharing product knowledge with case processing team for real-time understanding of product trends and developments. This is also very conducive to real-time signal detection, allowing more effective risk management activities.

- Safety Surveillance services collaborates with clients to provide signal detection, (for cases and signals) and evaluation work to monitor and track global product compliance changes that might have an impact on labelling requirements or necessitate a change to the safety profile of the product.
- MedDRA coding and writing risk management plans.
- Aggregate reporting(PSURs/PADERS/PBRERs/DSURs)
 - a. Periodic benefit/risk evaluation reports (PBRERs)
 - b. Periodic safety update reports (PSURs)
 - c. Periodic adverse drug experience reports (PADERS)
 - d. Summary bridging reports
 - e. Developmental safety update reports (DSURs)
 - f. Pharmacovigilance risk assessment committee (PRAC) responses/health authority responses.
- Electronic reporting set up (By E2B format).
- Contractual agreement production and maintenance
- Risk management planning and services.
- Due diligence support activities (The due diligence should be supplemented with data on the tenure of the staff and management team).
- Provide insight and overview of global regulations.
- PV Training (The sponsor drug safety team provided initial training to the CRO staff at the beginning of the relationship, the CRO is responsible for training new staff (train-the-trainer principle).
- Quality compliance training and review (Reducing costs through low-cost or off-shore outsourcing results in quality issues and regulatory non-compliance and deviations. It is pertinent to maintain the necessary oversight and engagement with the outsourcing partners or the vendors).
- Audit and inspection readiness and preparation. (A track record of regulatory compliance and low non-conformity rates usually indicates a robust quality management system. Audits during the cooperation either by in-house staff or an external auditor are the best tools to reconfirm that the provider meets quality standards and implements adjustments in a changed regulatory environment.
- Clinical safety assessments.
- An experienced QPPV (Qualified Person) service only, LPVRP (Local Pharmacovigilance Responsible Person) service, report writing services or an entire team, service providers are able to provide subject matter expertise for matters pertaining to complex global pharmacovigilance and Medical Information regulations, expertise which may not be readily available in house).
- Most countries have requirement of LPVRP/QPPV. If you are exporting your drugs to any international market, it is critical to have their respective supports.

- Regulators prefer dealing with senior professionals experienced in pharmacovigilance and having a single point of contact to address their queries and concerns. It is helpful if these are in charge of the entire pharmacovigilance operations in their region.
- QPPV should be 24x7 available.
- The role of QPPV and/or the deputy can be outsourced, however this must form part of a formal agreement which will have clear definitions of the responsibilities of each party, moreover confidentiality must be maintained.
- A QPPV has a central role focused on ensuring the company is meeting all of its PV responsibilities and ultimately the safety of the public using the medicine is maximised.
- Labelling documents/ RSI's Updating revision (CCDS/CCSI/PIL/SPC assessments)
- SOP writing/updating/ Training (SOPs preparation / review and updating and of other controlled quality documents is also offered by consulting services.

Conclusion:

Outsourcing pharmacovigilance activities is a standard business practice in a rapidly expanding market segment. It can be successful provided:

- a. The service provider has the qualification for the pharmacovigilance services.
- b. Contractual agreement includes well defined responsibilities.
- c. Transparency maintained at project start.

References:

1. Pharmacovigilance Outsourcing – When is it right for you retrieved from <http://www.pharsafer.com/pharmacovigilance-outsourcing-when-is-it-right-for-you/> on 17-Oct-2015.
2. Effective Safety Monitoring of Established Healthcare Products retrieved from <http://www.pharmoutsourcing.com/Featured-Articles/150931-Effective-Safety-Monitoring-of-Established-Healthcare-Products/> on 18-Oct-2015.
3. Stepping into the future of pharmacovigilance retrieved from https://www.parexel.com/files/2014/2437/7927/PAREXEL_Stepping_Into_The_Future_Of_Pharmacovigilance.pdf on 18-Oct-2015.
4. The importance of a global delivery model for pharmacovigilance: The right mix of local presence and offshore capabilities retrieved from <http://www.sciformix.com/wp-content/uploads/PharmaOutsourcing-Global-Delivery-Model-for-Pharmacovigilance.pdf> on 18-Oct-2015.
5. Accenture accelerated R & D services: Pharmacovigilance services retrieved from <https://www.accenture.com/us-en/service-life-sciences-pharmacovigilance-drug-safety.aspx> on 19-Oct-2015.