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Future of pharmacovigilance (PV) outsourcing in India

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Abstract

Over the past few decades, many high-profile drug recalls, regulatory authority warnings and negative media impact have caused monetary losses and tarnishing of the image of pharmaceutical companies. Consequently, these companies have invested heavily on PV systems.

For a pharmaceutical company, setting up a PV system in-house is not always cost effective and finding qualified and trained resources is a huge challenge. Thus, these companies have relied on PV outsourcing to markets such as India. This white paper provides an overview of the current PV outsourcing market in India and a prediction into the future of PV outsourcing in India based on current trends in the PV world.

Keywords: Pharmacovigilance outsourcing, service providers, contract research organization (CRO), business process optimization (BPO), outsourcing market, SWOT analysis, SMAC, text analytics

1. Introduction

There has been an ever increasing pressure on pharmaceutical companies with respect to proactive detection and management of safety signals or concerns related to the use of a medicinal product and grave concerns regarding public health impact. This along with strict regulatory requirements has sparked the exponential rise of the global PV market. Many high profile drug withdrawals (e.g. Vioxx i.e. rofecoxib from Merck that was recalled in 2004) in the past decade has led to various pharmaceuticals to adopt Good PV Practice guidelines in a more stringent way. These factors are expected to drive the growth of the global PV market.

As per a market research report by Transparency Market Research¹, the global PV market is expected to grow at a Compound Annual Growth Rate (CAGR) of 13-14% to approximately USD 6 billion by 2020. According to this report, in 2013, post-marketing safety surveillance accounted for over 60% of the PV market. Post-marketing safety surveillance involves active collection, analysis and interpretation of safety data concerning the marketed drug. These data are used in the benefit-risk assessment of the medicinal product as well as formulating a risk management plan and risk minimization measures.

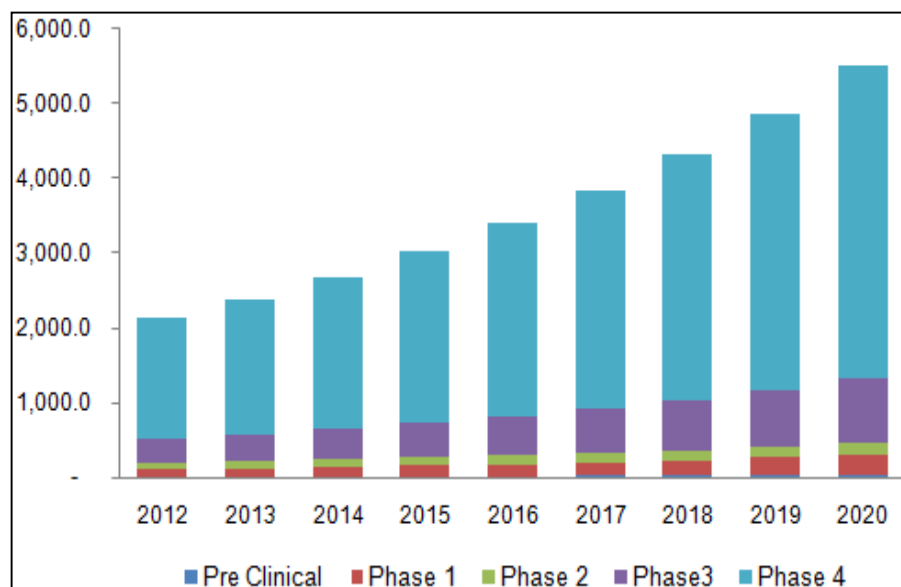


Fig 1: Global PV market, USD million (2012 – 2020)²

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PV activities in any pharmaceutical company are either done in-house or are outsourced to Contract Research Organizations (CROs) or Business Process Optimization (BPO) providers. The CROs had a substantial share of over 50% in the PV market in 2013. This segment is estimated to grow further as CROs are deemed as a cost-effective solution for PV activities. The major names operating in the PV market are Covance, Parexel, Quintiles, Cognizant Technology Solutions, Accenture, Tata Consultancy Services

(TCS), Wipro, etc. to name a few.

2. Overview of the outsourced PV activities in India

PV outsourcing generally involves the handover of certain processes involving drug safety to a third-party provider or a vendor. These generally include core PV activities like case processing to governance activities like maintaining compliance. The various PV activities that are currently outsourced to India are presented in the figure below.

| Collection of ADR data | Individual Case handling | Periodic reports | Signal management | Risk Management |
|--|--|--|---|--|
| <ul style="list-style-type: none"> Data entry Triage Call centers | <ul style="list-style-type: none"> Case processing ICSR - medical review | <ul style="list-style-type: none"> PSURs/PBRERs DSURs PADERs Benefit-Risk assessment | <ul style="list-style-type: none"> Signal detection activities Literature search and evaluation | <ul style="list-style-type: none"> Risk Management Plan Labeling updates |

Fig 2: Outsourced PV activities in India

(ICSR: Individual case safety report PSUR: Periodic Safety Update Report; PBRER: Periodic Benefit Risk Evaluation Report; DSUR: Development Safety Update Report; PADER: Periodic Adverse Drug Experience Report)

Apart from the core PV activities, certain other PV related activities are also outsourced which include but are not limited to electronic Common Technical Documents (eCTDs), Standard Operating Procedure (SOP) preparation and management, compliance monitoring and reporting, trend analysis, inspection readiness and audit preparation and

Corrective and Preventive action (CAPA) implementation.

The current PV outsourcing market in India is dominated by case handling activities that involve case processing (in the safety database) and medical review of ICSRs. As far as ICSRs are concerned, pharmaceutical companies prefer to outsource the entire process from triage to regulatory submissions to a single vendor. However; when it concerns certain niche activities like aggregate reports or signal detection, these companies generally outsource parts or certain processes or steps involved in these activities.

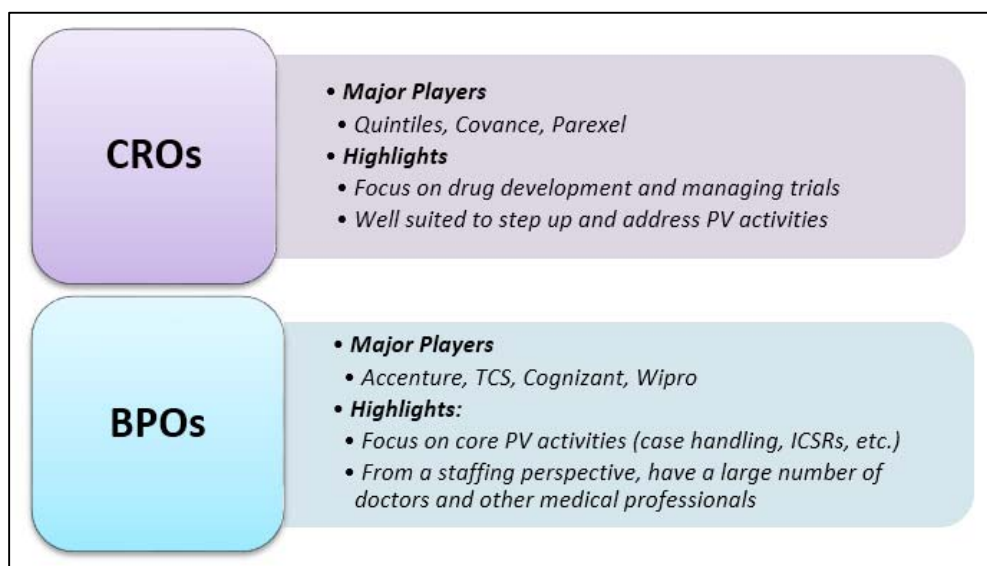


Fig 3: Service providers for PV outsourcing activities

3. Advantages of PV outsourcing

Outsourcing PV activities can benefit the pharmaceutical company in various ways including:

- Cost-cutting and budget management
- Increased business capacity management through the vendor
- Increased efficiency of the PV process

- Increased Return on Investment (ROI)
- Pharmaceutical companies can concentrate on core PV activities and allocate resources more effectively and efficiently

4. Future of PV outsourcing in India

India has witnessed an immense growth in the CRO industry

in recent times and is estimated at USD 2.5 billion³ market in 2013 and until 2020 it is estimated to grow at a CAGR of 18-20%³.

India has been delivering Information Technology (IT) and IT-related services efficiently in the past and now India is the

go-to place for outsourcing PV functions. A Strengths, Weaknesses, Opportunities and Threats i.e. SWOT analysis of the Indian PV market with respect to outsourcing is presented in the figure below.

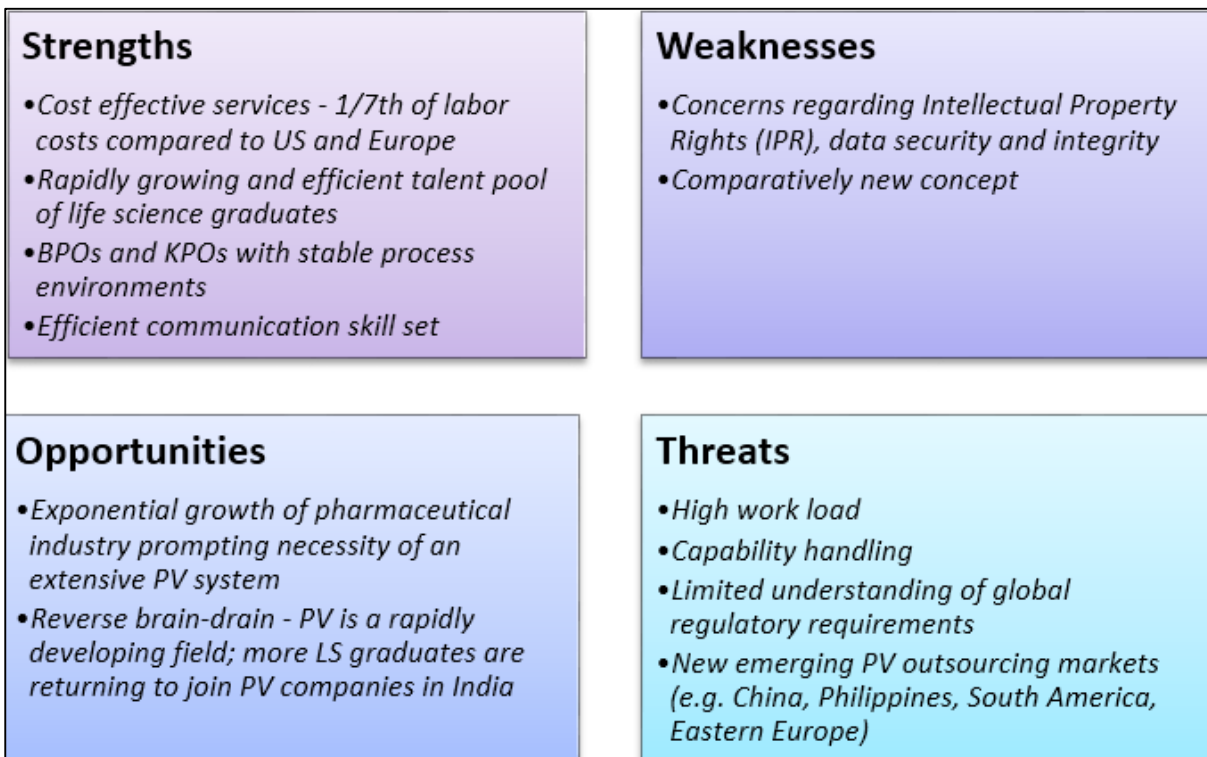


Fig 4: SWOT analysis of Indian PV market

India is the preferred destination for PV outsourcing considering low cost, high skill set and fluent English language users. The major advantage of the Indian outsourcing market is an extensive availability of educated professionals and a large pool of doctors and pharmaceutical professionals. Over the past decade, many renowned pharmaceutical companies (e.g. AstraZeneca, Pfizer, Novartis), some even featuring in the top of the Fortune 100 list, have set up PV centers in India either by way of independent units or by forging strategic alliances with PV service providers, thereby creating huge employment opportunities. For the past few years, CROs and BPOs involved in PV activities are performing well in India, thereby making India a favored choice for PV outsourcing amongst pharmaceutical companies. Another example is Parexel’s acquisition of Quantum Solutions India (QSI – an established Indian PV outsourcing vendor) in 2015⁴. This move has enabled Parexel to provide a wider range of PV support to its customers.

Over the past few years, with technological innovation, standardization and global optimization of talent, the PV domain has witnessed an industrialized growth. Considering the increasing pressure of cost-cutting and budget restrictions on pharmaceutical companies, the future of PV would be driven by automation, artificial intelligence or robotics. Businesses in the current era are defined by newer technologies such as Social Media, Mobility, Analytics and Cloud computing (SMAC). These technologies have the potential to transform any business and upscale it with respect

to capability and performance. Therefore, ‘digitizing’ business is one of the top priorities for many business models and PV outsourcing industry is no exception. Indian PV outsourcing companies especially from the BPO sector are exploring this sector to optimize their business model.

Certain service providers are turning towards analytics to boost their PV capabilities. Such analytic software can change the face of data mining in signal detection and management. One such example is the “Text Analytics” for PV. This analytic tool processes large volumes of unstructured text and classifies or groups it accordingly. This analytic software can help generate adverse events from various therapeutic reports, establish drug-event associations and report suspected new cases. Such innovations will foster additional capability in the business model and will attract more business.

Finally, the government led initiatives like the PV Program of India (PvPI) primarily to increase the safety and awareness related to the use of a medicinal product and adverse event reporting will only further foster the growth of PV market in India. This would not just be limited to outsourcing but “in-sourcing” as well.

5. Conclusion

To abide by stringent regulatory requirements, any pharmaceutical company’s PV system needs to be compliant and robust. This has increasingly put a dependence on vendors or third party providers which is evident from the growth of the PV outsourcing industry. This dependence is expected to grow further due to a rapid growth in the

pharmaceutical industry.

India provides a cost-effective and reliable option for PV outsourcing to large and small pharmaceutical companies. Apart from commonly outsourced PV functions like case handling and data entry, it is the other high-end, niche activities (e.g. signal management and aggregate reporting) that will drive the future growth of the PV outsourcing industry in India. Process optimization, global operational models, innovative thinking, automation tools, amalgamation of IT skill set (e.g. SMAC) with PV services along with a talented pool of medical, paramedical and non-medical professionals will ensure the continued growth of PV outsourcing industry in India.

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