How to Streamline Your Global Pharmacovigilance Management Process While Reducing Costs

By Michael Smyth, General Manager, TransPerfect Life Sciences Solutions

TRANSPERFECT

Since TransPerfect's founding more than 20 years ago, the pharmaceutical industry has undergone a radical shift. Due to frequent mergers and acquisitions, the number of large pharmaceutical companies has shrunk significantly. At the same time, the pool of smaller companies that develop products—and at times license or sell these products to the large players—has grown.

This evolution has created a reliance on outsourced partners to support the development, commercialization, and lifecycle management of products for the life sciences industry. The CRO market today is valued at $23-25 billion with analysts estimating it will reach a staggering $33 billion by 2018. While that number may seem high, it reflects only 30-35 percent penetration of an R&D spend of $90-95 billion, but expectations indicate that that percentage could climb to 60 percent in the long term[1].

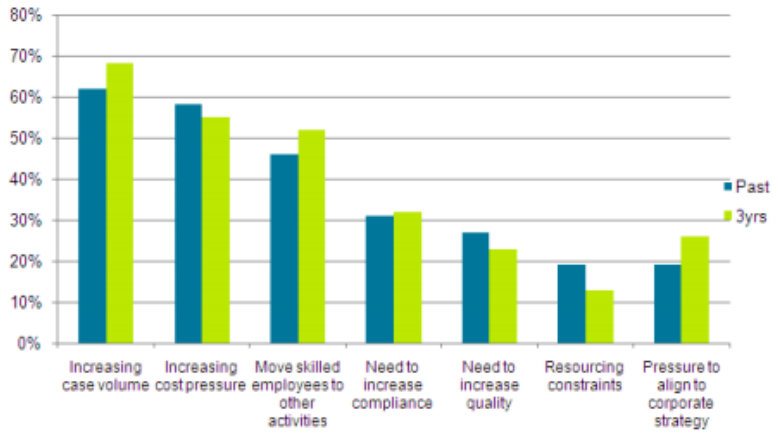
When we look at what were considered to be "full-service" CROs in the 90s, the services available then were significantly different from today's offerings. Clinical Trial Management, Data Management, Biostatistics, and Medical Writing were then considered to be full-service. While some CROs had safety departments, pharmacovigilance services and technologies were not offered by CROs, as most activities were kept in house by the sponsor.

Fast forward two decades, and we see a brand new model—a result of the life sciences industry gaining a greater understanding of its core competencies (i.e., which services and technology do they need to keep in house versus which can be outsourced to a competent provider, allowing for a lower balance sheet number). Given their narrower scope, external providers can scale in a way that life sciences companies cannot. Large CROs are seeing significant growth, as well as a rising number of vendors who have seen the need for specialized services and are filling the gaps.

Pharmacovigilance is a particular area that has seen, and will continue to see, significant growth. Regulatory bodies are becoming increasingly concerned about serious side effects, many of which only become apparent once a product has launched and is made available to the patient population. As a result, pharmacovigilance has become even more important. Evidence of the heightened focus includes the requirements for companies to have a Risk Management Plan in place that will be launched for any new product, as well as the European Medicines Agency (EMA) publishing new guidance in 2012 with the Good Pharmacovigilance Practices (GVP).

The GVP modules that have been finalized (or are in draft) are focused on key areas of improvement for pharmacovigilance, with different timelines for each module to come into effect. The GVP regulations will require companies to become a Marketing Authorization Holder (MAH) for any product launched under the EMA. Japan's regulatory authority, PMDA, is increasing its pharmacovigilance oversight with impending regulations and projects designed to improve safety monitoring for the consumer. The MIHARI project will, amongst other things, make safety information from post-marketing studies available electronically, while simultaneously creating a database of the information[2].

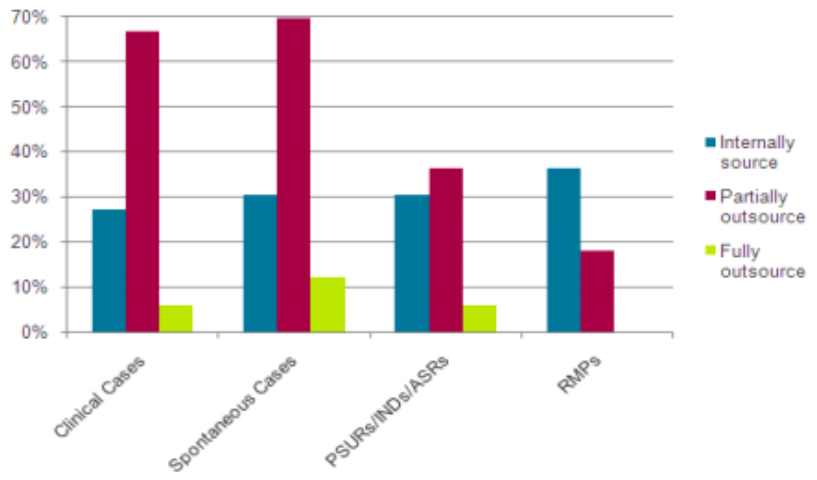
As regulations increase, more resources are required to support companies' pharmacovigilance activities. Pharmaceutical companies, and soon medical device companies as well, will be challenged with figuring out how to support and streamline the management of pharmacovigilance. In the past five years, we have seen companies shift away from purely tactical outsourcing in favor of a more strategic approach. Shown in the figure at right, increasing case volume and cost pressure were reported as the most significant factors driving pharmacovigilance outsourcing[3].



This data comes from the pharmaceutical industry, but medical device companies will likely follow suit, as they have in other areas in the development and marketing of products.

1 http://www.resultshealthcare.com/media/114306/20131128_cros_and_other_outsourced_pharmaceutical_support_services_m_a_drivers_and_trends.pdf
2 http://www.pmda.go.jp/regulatory/file/english_presentation/safety/S-E2hori.pdf
3 http://www.wcigroup.com/Pages/Thought%20Leadership%20Articles/Sourcing-Pharmacovigilance-Activities---Strategic-or-Tactical-Imperative.aspx

WCI conducted a survey and found that by 2012, companies were expecting to adopt the following process for pharmacovigilance activities related to outsourcing or retaining activities in house. As highlighted in the figure at right, almost 70 percent of case management is being partially outsourced. While this percentage may seem high, a shift to fully outsourcing these types of activities is expected in the coming years, as companies continue to look for ways to decrease costs.



The volume and visibility of pharmacovigilance cases will also increase in less mature markets including Asia, Latin America, and Africa. Currently, there is a lack of standardization for pharmacovigilance across Asian countries, which is due in part to varied geographical, cultural, and medical practices[4].

The Path Forward

As companies realize the benefits of moving to strategic—rather than tactical—outsourcing on pharmacovigilance, additional cost benefits will result. One recent study showed cost savings of 30-40 percent through executing this strategy[5].

There are myriad activities surrounding pharmacovigilance, but as development continues to occur on a global scale, it is critical to assess what needs to be done in house and what can be strategically outsourced to global partners. Some of the key ways TransPerfect Life Sciences can help in this endeavor during the development and launch of products include:

- Case Processing – Collection of Adverse Drug Reactions (ADRs) globally in real time is critical, as well as the preparation of the Individual Case Safety Reports (ICSRs). The ability to collect data in virtually any language around the globe is necessary in order to ensure accurate information. Reporting on Medwatch, CIOMS, etc., as well as the ability to provide data in an E2B format to systems including Argus™® and ARISg™, remain important requirements of any support provider.

- Global Call Center – While many providers claim to have a "call center," many only have support from 9 am to 5 pm in select regions of the world; lack the scale to process larger case volumes; and/or rely on an outsourced partner to deliver the language components. Choosing a provider with a dedicated global call center that can handle both inbound and outbound calls is important for companies with plans to launch new products or whose products are already being marketed.

- Technology – Any strategic support provider must be able to collect any cases received—whether ADRs, medical information, product complaints, or non-case calls—in a web-based database in order to support life science companies. Technology must be built for ease of use and, most importantly, it must meet the 21 CFR Part 11 requirements and be a validated solution.

- ADR Literature Monitoring – Literature searching can be done by many providers, but literature searches become more complicated in a global environment when products are registered in a country where English is not the primary language. A provider that can perform literature searches in any language, and provide the results of that search at the frequency defined by the life sciences company or its CRO partner, is essential.

- Pharmacovigilance System Master File (PSMF) – The content of the pharmacovigilance system master file should reflect global availability of safety information for medicinal products, with information on the pharmacovigilance system not just confined to local or regional activities. Many companies still maintain their PSMF documentation in hard copy, making real-time availability to regulatory inspectors, global teams, and partners impossible. A solution that is designed to allow near real-time access to global pharmacovigilance stakeholders and regulatory authorities is imperative to comply with the EMA's GVP requirements outlined in Module II. Employing a 21 CFR Part 11 compliant technology solution that fully supports a regulatory compliant PSMF can reduce sponsor or CRO burdens.

[4] http://www.jpharmacol.com/text.asp?2013/4/5/7/120941
[5] www.molecularhealth.com/wp-content/uploads/2013/12/Drug_Development_pharmacovigilance_2010.pdf

- Safety Notification Letter Distribution – Prompt distribution of IND Safety Reports to the FDA, Principal Investigators (PIs), and IRBs/ECs is critical to the global clinical development process. As outlined in 21CFR312.32, the sponsor must notify all participating investigators of any potential serious risks from clinical trials or any other source. Risks should be reported as soon as possible, but no later than 15 calendar days after the sponsor determines that the information qualifies for reporting as defined in the regulations. Companies need a rapid method for communicating with PIs that incorporates a tracking system for indicating whether the investigator reviewed the safety letters and notified the IRB/EC. Depending on the institution regulations, the letters may also need to be in the primary language of the IRB/EC. An automated tool that is 21 CFR Part 11 compliant is critical in order to streamline the process globally[6]. Not only do such tools provide comprehensive and real-time information to sponsors and CROs, but they eliminate the need for emailing, faxing, or worse yet, express-mailing the information—all of which are still used far too commonly at many life science companies and CROs.

- Translation – Though it may not seem core to the pharmacovigilance world, translation of safety information touches every point in the process, given that we develop and commercialize products in a global world. Having a standardized process across a sponsor or CRO is important in working efficiently when the need arises.

Thinking Strategically

As life sciences companies, support providers, and regulatory authorities throughout the world evolve, so too will the industry that provides a streamlined process for the conduct of these activities. We will continue to see companies move from tactical outsourcing to a more strategic model as they evaluate core competencies that need to be retained in house versus what can be leveraged with a true strategic partner.

[6] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32