Safety on a Budget

Four Strategies for Cost-Effective Pharmacovigilance

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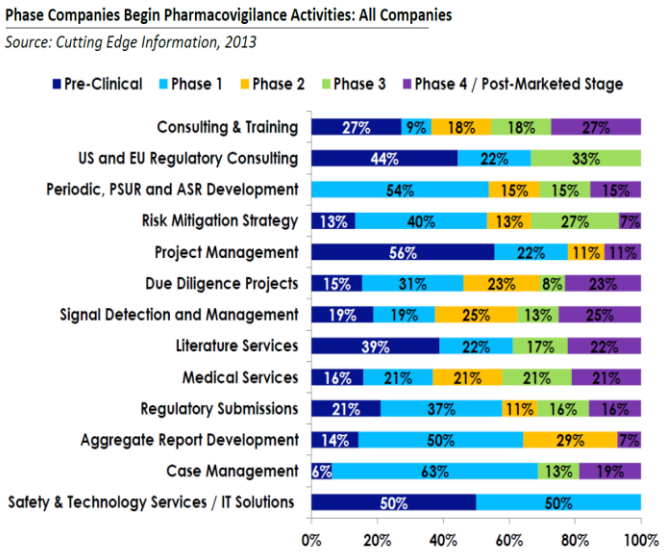
Among the pharma industry's concerns surrounding the urgent and increasingly complex issue of drug safety under difficult economic conditions, the most prominent topic of discussion is the question of outsourcing. Does outsourcing make sense for our company? How do we choose the right outsourcing partner? Can we be certain that outsourcing will not compromise our drug safety standards and leave us exposed to greater risks in the name of cutting costs?

Certainly, the trend in drug safety is to selectively outsource to qualified resources; however, outsourcing is not the only possible measure you can take to maintain safety as a top priority while still controlling costs. Following is a list of four areas of focus in which pharma companies, large and small, can take steps to make every dollar count. Some of these topics may seem elementary, but all are worthy of closer scrutiny and can contribute to an overall strategy for wisely allocating limited resources under escalating regulatory pressure to detect risks.

START EARLY

Drug safety ideally begins with an assertive safety plan that focuses not only on efficacy but also on safety data and risk-benefit information from early-stage trials. Historically, product development and clinical trial methodologies were primarily concerned with efficacy, as we all want our medicine to solve the problem for which it was designed. In a tightening regulatory environment, putting safety on a backburner until later stage trials can cost millions of dollars and waste precious time in resubmissions required to satisfy safety issues.

This concern is reflected in a 2013 industry survey conducted by Cutting Edge Information, in which a sample of large to mid-sized pharmaceutical companies reported that they began most of their drug safety activities in either pre-clinical or Phase 1.[1]



DON'T SHORTCHANGE THE DATA

Determining budgets for pharmacovigilance programs can sometimes be difficult given the amount of

uncertainty that exists in any safety program. The possibility of having to handle peak workloads or manage REMS issues requires that flexibility be built into budgets but that's not the only area in which flexibility is important. Considering the impact of scalable, intelligent data handling systems at the beginning of a program can possibly save money in the long run and in some cases, create totally new streams of revenue.

With systems in place that allow researchers to aggregate pools of data, they can more easily understand the safety profiles of their products and look for any interesting information or trends that might arise. This gives them a better chance of understanding both the risks and opportunities should the drug reach the market. But to mine data in this proactive way requires an information technology infrastructure that can support this level of analysis and query.

Regardless of who starts the conversation, the once-taboo matter of initiating dialog with the FDA seems to be moving in a positive direction.

For example, specialty safety management organizations and software companies have hosted solutions and tools that enable data to be aggregated without freezing the database. There are also signal detection tools that allow companies to analyze proprietary data from the safety database and compare information with external resources including, FDA's Adverse Event Reporting System (FAERS) and the WHO Database (Vigibase).

New ways of handling data are well worth considering prior to beginning a safety program because while many of these technologies come with a price, the value they bring in the long run – through improved success rates and opening unforeseen markets – can more than make up for any initial expense.

COLLABORATE WITH REGULATORS

Globally, regulatory agencies have been steadily increasing their expectations for proactive risk identification and communication. Fortunately, there are new ways to support pharma companies in their desire to shepherd drugs through the rigorous approval process while maintaining both budgets and high safety standards.

Many regulatory agencies, like the FDA and EMA, are adopting better methodologies to look at aggregate data. While this is helpful in supporting a product over its full life cycle, small to midsized companies don't always have the financial resources to accommodate the most effective signaling requirements; however, the costs associated with simply reacting to regulatory communication can be expensive and counterproductive to the marketability of a drug. If internal resources do not exist, outsourcing the REMS consulting and signal management functions to an organization that specializes in working with regulators can offer a cost-effective solution while providing the requisite oversight.

Regardless of who starts the conversation, the once taboo matter of initiating dialog with the FDA seems to be moving in a positive direction. FDA's ongoing Sentinel Initiative is aimed at promoting pharma companies' voluntary participation in the sharing of safety data, which has already begun to open up channels of communication between regulator and industry.[1]

FIND A PARTNER

If managing all of the elements required for an effective drug safety program seems cumbersome, outsourcing is an option that was not as prevalent 10 years ago as it is today. Specialty providers with proven, streamlined approaches to many of the common challenges can be less costly and easier to implement than creating and running a pharmacovigilance department in-house.

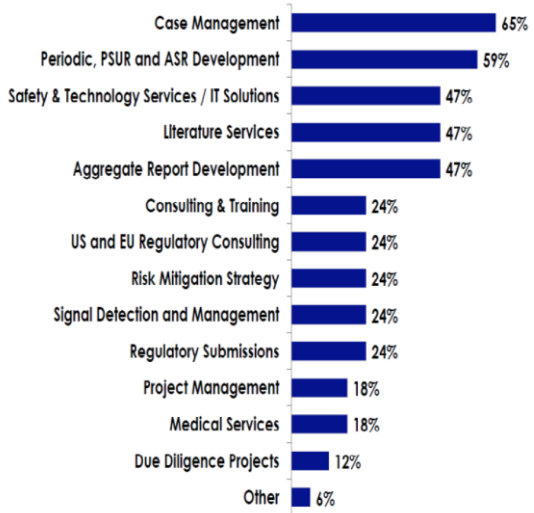
Outsourcers can provide comprehensive services to effectively support drug safety operations, which can include any combination of the following.[1]

- Pharmacovigilance for a specific clinical trial
- Generation of clinical trial annual safety reports and periodic safety reports
- Drug safety for post-marketed products
- Adverse event management
- Safety database management and data entry
- Development of safety specifications and risk management plans
- Signal detection and evaluation
- Ad hoc reporting to regulatory authorities
- Literature screening
- Process design and SOP development

The Cutting Edge Information survey found that outsourcing tends to be more prevalent among smaller pharmaceutical companies than larger ones, but all of the companies surveyed outsource at least some component of their drug safety activity.[1] Among these companies, the percentage of their drug safety budget that is outsourced varies widely, from 6% to 60% or more.

MOST COMMONLY OUTSOURCED DRUG SAFETY ACTIVITIES

Source: Cutting Edge Information, 2013



The survey identified case management as the most commonly outsourced drug safety activity (65%), followed by the outsourcing of Periodic, PSUR and ASR Development (59%). Case management and information technology are the most costly areas to build and maintain, yet the outsourcer can spread costs and resources over multiple clients while leveraging cost-effective, efficient processes built for the purpose of detecting emerging signals.

With outsourcing, start-up costs have a much lower impact on your budget in comparison with building an in-house safety program. Capacities to grow and scale with additional new products are made easier by established outsourced PV systems.

Many factors go into the selection process for outsourced drug safety vendors. One key consideration is the degree of responsibility to be turned over to the vendor. Drug safety vendors may provide either turnkey solutions or ad hoc services that can be selected individually, or they may offer both. In the Cutting Edge Information survey, 33% of respondents chose to outsource to those vendors offering both service models.[1] That level of flexibility can be a valuable asset given the constantly shifting circumstances and unpredictable workloads inherent to pharmacovigilance.

The product life cycle stage, covered by an outsourcing vendor, is important for decision-making purposes. Some vendors focus on the investigation phases while others specialize in post-marketing pharmacovigilance, and some companies are experienced in all stages. A drug safety partner's expertise needs to match your company's needs and product profile.

Other primary areas of consideration for outsourcing decisions:

- Ask a potential safety partner about early signal detection and the topics discussed above.

- Ask them about the number of years of experience their pharma case managers have.
- Ask for a ROI model that compares or addresses:
  - The number of case managers to total number of cases processed.
  - The number of database licenses to total number of drugs under safety management.
  - The costs of geographic expansion and regulatory filings for each drug introduced into the market.
  - Incremental costs that will be incurred to ensure the best proactive signaling service possible.
- Ask how certain key performance indicators (KPI) are tracked and managed.

The challenges of managing the balance between budget and safety can be mitigated by addressing any of these recommendations, but deciding on the degree to which your organization chooses to outsource can be difficult. As specialty pharmacovigilance companies continue to emerge, it's worth finding a partner who understands drug safety from a cost/benefit standpoint. Unless you manage 100% of your safety function in-house, this is one of the most effective ways to minimizing costs while protecting the safety of your patients and the longevity of your products.

NOTES

1 *Driving Pharmacovigilance Success: Risk Management Plans and Adverse Event Reporting*, Cutting Edge Information, July 2013

ABOUT THE AUTHOR

Elizabeth E. Garrard, *PharmD, RPh*, joined Drug Safety Alliance, Inc. with its founding in 2000 and served as Chief Safety Officer until 2012. Her responsibilities at DSA included leadership in strategic planning, analysis, development, implementation, and measurement of all aspects of drug safety, pharmacovigilance, and risk management. She has more than 30 years of clinical and regulatory experience spanning the pharmaceutical, clinical, pharmacovigilance, hospital, and retail industries.

ABOUT US

Founded in 2000 and acquired by UDG Healthcare plc in 2012, as part of its Ashfield Division, Drug Safety Alliance, Inc. (DSA) is a global leader in safety and risk management services supporting pharmaceutical, biotech, medical device, consumer health and animal health organizations. Exclusively focused on pharmacovigilance, DSA provides comprehensive outsourced solutions and modified services to augment existing safety departments. DSA is headquartered in Research Triangle Park, North Carolina. For more information, please visit www.DrugSafetyAlliance.com.

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