Why Aren't More Life Sciences Companies Automating PV Data Capture?

The pressures on pharmaceutical organisations to capture, sift and process real-world adverse event data are immense – and soaring. So why are safety and pharmacovigilance departments lagging in their application of smart technology, wonders John Price, a life sciences regulatory and safety consultant and advisor to Arriello.

Pharmaceutical companies must ingest, check, interpret and report vast quantities of real-world data about any untoward effects of human medicinal products, accurately and within a tight timeframe. This substantial undertaking is growing all the time, too.

Yet, compared with other functions across the pharmaceutical product life-cycle, safety and pharmacovigilance (PV) teams are the least likely to employ smart technology to help lighten the load. This is surprising, given that life sciences companies today spend a disproportionate amount of their PV budget just amassing reports of suspected drug reactions – when many of these reports are of very low quality, meeting only minimum criteria for validity or lacking key clinical information. Crucially, any resource that goes into processing this information is time, energy and budget that is not being expended on analysing safety information – to enhance the safe use of drugs by patients.

So what is holding companies back from proactive investment in solutions that could help them?

A Cost/Benefit Perception Bias

Organisations' lack of investment in smart solutions, certainly among organisations that lack the scale and internal IT resources to develop their own, can be put down in part to PV's perceived lack of strategic priority compared to pre-marketing authorisation activities such as clinical trials.

In the latter case, technology is seen as a means of accelerating products' speed to market, expanding the target opportunity, and bringing in new revenue. PV, by contrast, is seen as a 'cost centre'; a public health obligation which adds little value for the business.

This is lamentable, given the scope for process transformation that today's technology enables. Proven solutions exist now which could transform the efficiency, effectiveness and regulatory adherence of PV processes, without placing data at any risk of being compromised in any way.

Among the large household pharma names, technology developments probably are taking place, but internally. Typically, the major global players still prefer to build their own customised solutions, keeping these shrouded in secrecy as though they might offer some kind of strategic advantage and competitive edge. Yet this approach is perplexing. While Big Pharma clearly has the resources to develop its own solutions for adverse event (AE) case intake and processing, companies would surely be better off spreading cost, and increasing speed to effective solutions, by using ready-to-go tools which have been designed to cater for most needs – many of which have been tried and tested many times over. Ultimately, there is little competitive differentiation in tasks that are first and foremost a public health activity designed to protect patients, as well as a regulatory necessity – so why reinvent the wheel?

A Focus on Quantity Over Quality

To fulfil their responsibilities, stay on the right side of regulators, and maintain public trust, companies have no choice but to do PV well, and report AE cases promptly. Without technology, this is a highly labour-intensive undertaking. It also requires specialist skills. Beyond life science and healthcare qualifications, PV demands the ability to interpret complex medico-scientific data – sorting significant and meaningful findings from distracting 'noise'. The perfect blend of pharma and data science skills is relatively scarce, as demonstrated by the difficulty companies report in recruiting qualified personnel. It is imperative, then, that companies apply that expertise economically and where it is needed most: to identifying and evaluating incoming signals, and addressing safety issues.

Even if organisations do see PV first and foremost as a cost centre, it is one that warrants investment as a means of providing services more cost-efficiently – without compromising PV quality or integrity. To put this need into perspective, financial market watchers such as Grandview Research and Market Watch estimate that the annual global spending on external PV solutions and services – currently *$5 billion* – is expected to more than *double* over the next few years. That's a substantial outlay, making services very expensive – and with a limited return on investment.

In an industry as competitive and cost-laden as the global pharmaceutical industry, organisations would do well to free up a healthy proportion of that resource, to channel into developing new drugs – as long as they can do so without risking patient safety; that is, without cutting corners.

The Case for Intelligent Investment

In the right hands, advanced technology can reduce errors to drive up PV accuracy while simultaneously driving down operational costs over time. Efficiency gains of between 60–70 per cent have been predicted, where companies are targeting largely manual and resource-intensive processes with intelligent automation, and higher efficiencies are perfectly possible; the kinds of innovation which don't require a wholesale overhaul of firms' existing PV systems. This includes case intake solutions which frontline professionals can use on the go, to capture AE details for straight-through processing.

As a rule-based activity, AE case processing lends itself perfectly to automation. There is no reason why a report made by a healthcare provider, patient or drug company representative via a smartphone app, for instance, couldn't be triaged, databased and routed automatically – according to the information in the report – to company staff or regulators, with minimal human intervention. The added benefit of such an application (in-the-moment computer-aided collection of information from the reporter) would be the

promotion of 'right-first-time' capture of comprehensive, high-quality case information at source – reducing the need for case follow-up. The convenience of such a system would save time for all involved, and enable more effective PV.

PV at a Crossroads

For now, applications that automate discrete PV activities, available from specialist PV IT providers, offer opportunities for incremental efficiencies to smaller companies with modest budgets who could otherwise be left behind in the imminent PV automation revolution.

As long as large pharma brands continue to focus their resources on developing their own customised PV solutions, mid-sized and smaller firms have a chance to peruse the market for off-the-shelf solutions or managed services which employ such aids to improve the quality and value of PV delivery.

The current window of opportunity is finite, however. Once the potential of emerging solutions has been proven, demand may already have consumed all the available capacity of technology service providers, leaving companies without the help they now desperately need. So timing any process transformation/smarter tools use is likely to prove critical.

John Price

John Price, owner and MD of John Price PharmaSolutions LLC, is a life sciences regulatory and safety veteran and consultant. Formerly holding leading safety roles at Alexion, Johnson & Johnson, and Pfizer, and now an advisor to PV managed service provider Arriello, John has in-depth experience of the evolution of pharmacovigilance, extending back to the late 1980s/early 1990s. This includes a rich understanding of industry best practice, and the potential of intelligent automation in the drive towards high-quality, compliant AE reporting and improved patient safety.

Web: www.arriello.com
Email: drjsprice@pharmacovigilantes.com