

Networking to reduce risk

Pharmaceutical and biotech organisations carry the responsibility for their patients' safety. In these businesses, drug safety is a life-critical process where these organisations are responsible for reporting and managing all adverse drug reactions and associated risks. It's a highly regulated aspect of the business, with the EMEA and FDA watching over in Europe and the USA.

It's also one that is constantly changing. Not only has there been an increase in the number of adverse events and the complexity of new drugs, but new legislation is often introduced, and existing regulations are continually updated. Compliance is rigorously monitored, and organisations are subject to reporting rules and audits. The price to pay for non-compliance is high – warning letters that risk the global reputation of the drug safety teams, and product withdrawal, which can cost the company millions of dollars and many staff jobs.

While drug safety can be a source of competitive advantage, there is a greater mutual benefit in sharing experience and common challenges. Drug safety people have many opportunities to network on a personal level, and in an industry where there are numerous regulations and requirements that broaden and deepen on a daily basis, opportunities for debate with colleagues facing similar issues are vital. There are national and regulatory working groups that enable people to meet and discuss the changing regulations. The conference circuit is another channel that allows drug safety personnel from different companies and countries to get together and debate the challenges they are facing, away from the office.

However, although these avenues have proved invaluable for debating and creating a personal network, there is still a need to share actual data and compare detailed levels of activity. With a further need to share ideas on how to tackle the hot issues – rising costs, signal detection and risk management, discuss trends and benchmark their performance. If you thought you had a good process in a certain area, how could you be sure? Companies were aware they needed to take a more proactive approach. This needed to be in a neutral environment, dissolving the worry about who would see confidential information. People wanted to get together but needed a trusted partner to facilitate.

pvnet™, a neutral drug safety forum, was created by drug safety experts WCI to facilitate this networking opportunity, and eleven of the leading pharma companies, as well as consultants and lawyers, now participate in it.

Pharma is an industry where there is ongoing debate about the right way forward. If something new and topical comes up, for example a topic such as signal detection, pvnet™ enables the members to share their understanding of what is taking place. They are then able to arrive at group consensus of

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a proactive approach going forward. The shared information allows members to critically assess the experience of others and build on these themselves.

To encourage better knowledge share a strict code of conduct protects data identity and forum integrity. The forum's content and focus has evolved since its conception; members control the topics that are focused on, which allows them to go into detail on practices in different companies. The processes discussed can be linked to performance in quality, compliance, productivity, and cost and can tell staff more about this business. Members are now requesting year-on-year trending of major measures as well as quantitative data, demonstrating that pvnet™ is now a well established and important component of the industry's drug safety function.

pvnet™ offers members a variety of activities, including an annual qualitative and quantitative benchmark study covering all aspects of performance and key processes based on self assessment. Alongside this, best practices have been brought to life through detailed questionnaires and process mapping which has enabled the group to challenge the status quo and drive strategic thinking.

The biannual session has succeeded in providing insight, facilitating debate and formulating the future for drug safety. For example, during the meeting a discussion on the EU Clinical Trials Directive and the FDA proposed rule on safety reporting requirements was held and in parallel, other participants talked about the legal imperative on drug safety.

pvnet™ is about networking, with the objective of future success for the participating companies, in part based on applying what they have learned from the forum in their own organisation. It has proved that networking can successfully improve the quality of pharmacovigilance data which can be integrated profitably into the business to improve practice and enhance performance.



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