Pharma Intelligence
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The Future For Pharmacovigilance Is End-To-End Outsourcing

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The Future For Pharmacovigilance Is End-To-End Outsourcing

The volume and complexity of safety monitoring now required for new and established medicines are driving pharmaceutical companies to rely increasingly on outsourcing of pharmacovigilance responsibilities. According to Global Market Insights, the worldwide market for PV outsourcing was worth more than $3.8 billion in 2019, and will expand at a compound annual growth rate of around 15.8% to reach $10.6 billion in 2026[1] .

One factor in this dynamic growth is sharp year-to-year increases in PV reporting to regulatory authorities. The European Medicines Agency, for example, noted that the number of suspected adverse drug reactions processed through its EudraVigilance system rose by 37% to more than 2 million in 2018, building on a 19% increase to nearly 1.5 million in the previous year[2]. Reports of serious adverse reactions alone via EudraVigilance rose from around 1.1 million in 2015 to some 1.4 million in 2018.

PV reporting has gained momentum as pharmaceutical products become more sophisticated and more precisely targeted to individual patients. Other drivers are more stringent regulatory requirements (including greater reliance on in-market and real-time monitoring); globalization and national variations in regulatory frameworks; growing engagement with stakeholders (e.g., healthcare professionals, patients) through digital technologies; and the proliferation of digital channels (e.g., social media) that demand closer tracking of unstructured safety data.

The consequences of drug withdrawals or supply interruptions due to safety concerns remain potentially cataclysmic. As a result, companies are under constant pressure to realize efficiencies, economies and flexibilities in their PV operations, by reducing dependence on in-house resources and expertise. Traditionally, though, the rigors of regulatory scrutiny and compliance have made industry reluctant to give up more control over PV functions.

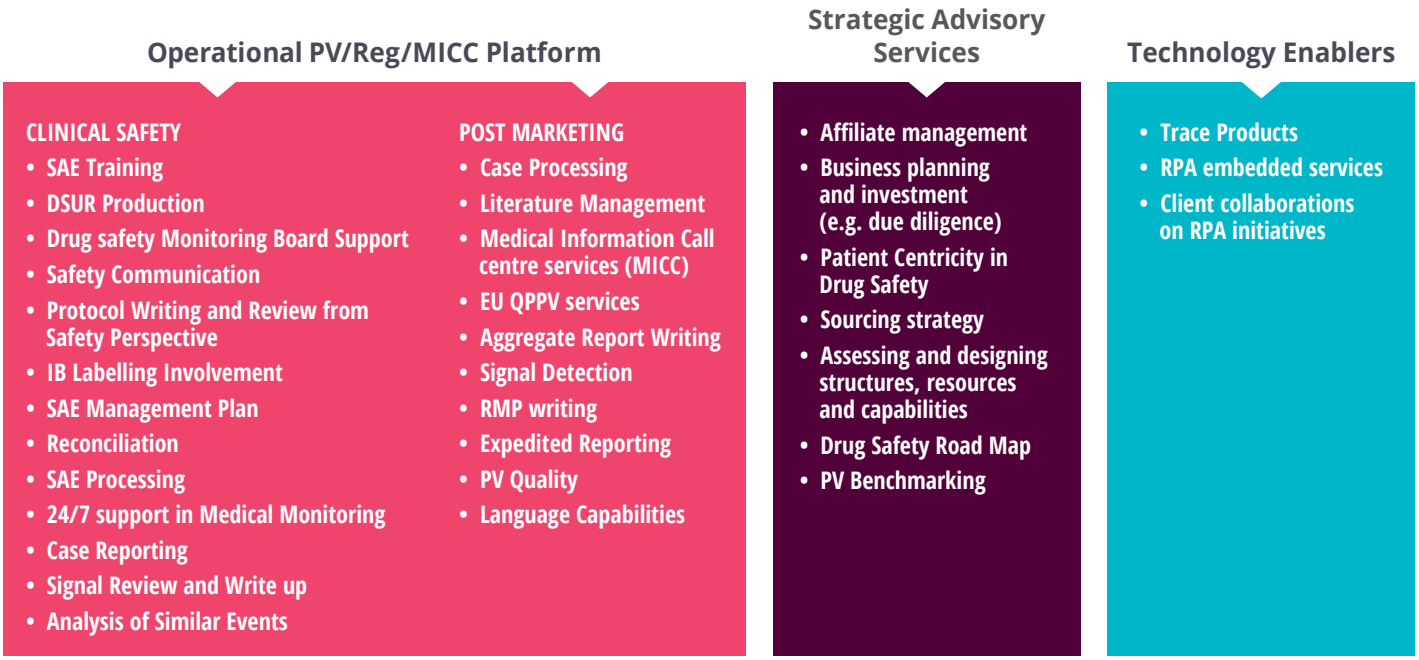
Nonetheless, in recent years companies have become increasingly comfortable with outsourcing relatively low-risk transactional PV functions, especially in the post-marketing space for well-established medicines. Outsourcing also provides access to new ideas, specialist expertise, innovative technologies and a broader overview of the PV environment. It reduces fixed costs and releases internal capabilities to focus on higher-level strategic or analytical safety management.

TOWARDS END-TO-END OUTSOURCING

The question now is how much this trend can accommodate outsourcing of end-to-end PV capabilities, not just in case processing, aggregate reports or literature reviews, but in clinical-phase PV, standard operating procedures (SOPs), pharmacovigilance quality assurance (PCVQA), risk-management plans, signal detection, inspections or audits. For Bioclinica, a global safety, regulatory and compliance specialist, that transition is already underway.

It also includes significant expansion of the company's delivery hubs in the US, the UK, India, China and Japan. "We're seeing an increase in the number of end-to-end PV requests for proposals coming in," says Humaira Qureshi, Bioclinica's president, drug safety solutions. "And companies that used to, maybe a year or two ago, restrict their outsourcing to case processing and aggregate reports, are now thinking, 'maybe I could do more'. "

Key Services And Capabilities



A low-cost, fit-for-purpose framework for comprehensive PV activities, including data-collection portals and SOP suites, could be particularly attractive to smaller companies in early clinical development, Qureshi points out. These companies may lack the budget and resources to establish their own PV capacity, or the regulatory knowledge to take new drugs all the way to market.

"They've got life-changing compounds in the pipeline and great data, they're very keen to develop the compounds and then potentially to either partner or divest these assets or progress to market very quickly," Qureshi elaborates. "They don't necessarily have the budget for a full safety system. But they need to satisfy auditors and regulators, so they can maintain their compounds within a compliant safety framework. We can offer them suites of ready-made SOPs, mailboxes and portals for data collection, and fit-for purpose systems, together with cost-effective alternatives to [Oracle] Argus and ArisGlobal, because the volumes are going to be lower."

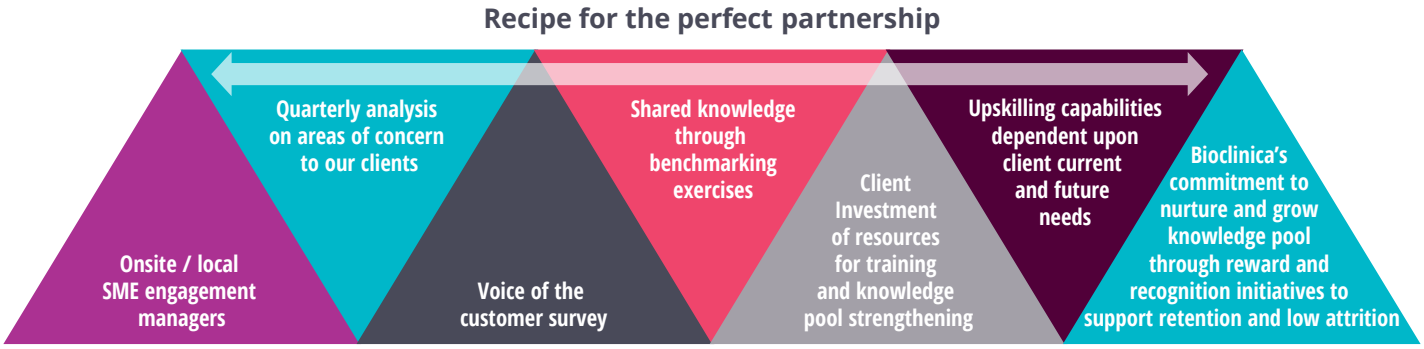
With automation gaining pace in the sector, Bioclinica is also building capabilities to handle outsourcing of higher-value medical, analytical and scientific thinking around PV. According to Qureshi, up to 75% of all in-house PV activities are now under review as not just transactional but as low-risk for outsourcing. "Any form of post-marketing is not an issue," she adds. "There's absolute nervousness about outsourcing clinical cases, but that is now changing rapidly. It's changing because we are reacting and adding more physicians and experienced scientists to manage products of greater complexity."

With this more permissive attitude to outsourcing come opportunities for economies of scale. "The greater the volumes and the scope we're getting, the more strategic and cost effective the partnership becomes," Qureshi explains.

UNDERSTANDING STRATEGIC DIRECTION

It is vital, though, in this context that a service provider understands the client's strategic direction, taking into account available budgets and their optimal distribution, return on investment, resource needs, year-on-year benefits, and the ideal duration of the relationship. "If your short-term ambition is to obtain high-quality data on a

Bioclinica's Successful Strategic Competencies



compound, and then partner or divest it, then all you need is a fit-for-purpose system that delivers cost-effective, high-quality solutions," Qureshi comments.

If the client prefers to invest in technology in-house to streamline transactional activities such as case processing, the provider can still adapt and evolve to offer end-to-end services in areas such as SOPs, aggregate reports, quality assurance and literature reviews. More often than not, this is based on the provider's consistent record of quality, consistency and productivity in these or related areas.

"Our clients really want to partner with us so that they can understand how to introduce cost savings into their PV model," Qureshi says. "The questions they typically ask themselves, ahead of outsourcing, include: what activities do we undertake in-house, and what resources can we offer to support these? What is something that truly can be outsourced, and what is something that can only really be managed in-house?"

Ordinarily, a company with assets in development might want to "keep its high-value staff in house to drive products from the early stages of clinical trials all the way through to Phase III, before the products can be outsourced", she adds. "But that's not to say a strategic partnership with a service provider will not deliver the same level of quality."

As PV service providers evolve, "we have to be strategic", Qureshi emphasizes. "We need to be able to offer more and more to our clients to help them make informed decisions. So, with aggregate reports, even though they are complex, having service providers with more physicians, more scientific thinkers, is going to help clients to process or evaluate, and subsequently disseminate, those data."

EMBRACING ACCOUNTABILITY

Even in more sensitive areas such as quality assurance, "there is definitely a trend to see what more we could do with remote quality-assurance support such as audits", Qureshi says. She acknowledges that more progressive PV outsourcing tends to mean more frequent regulatory inspections and increased client exposure to audits and inspections.

Consequently, willingness to embrace accountability is paramount. "A good strategic service provider will always view themselves as part of the client's team, not as a separate entity," Qureshi stresses. "As part of a package, we are your team and we are answerable to the inspectors when they come."

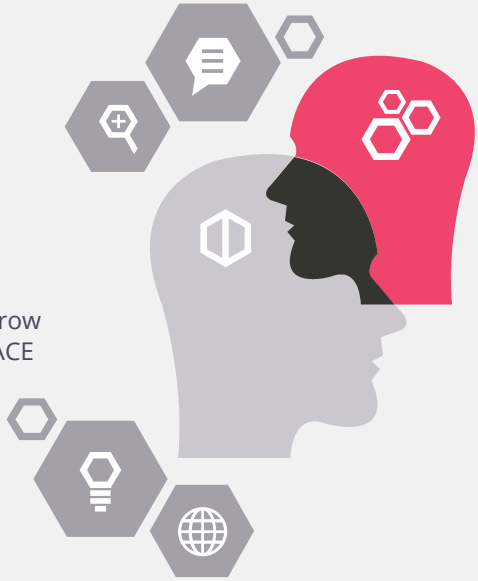
Also critical to the relationship are transparency and communication, especially as clients are worried about training, quality and knowledge retention for products in clinical development and beyond. Bioclinica offers real-time vendor oversight as part of its PvTRACE technology.

"It's about making sure that systems are in place to satisfy client oversight," Qureshi says. "That could be through

Integrated Technology For Next-Generation Drug Safety. PvTRACE

We at Bioclinica understand the pharmacovigilance industry, its legislative requirements and the challenges of our clients to provide you with a unique and bespoke concept in PvTRACE that no one has offered yet.

- **Real-time vendor oversight management**
- **Real-time case lifecycle status – monitoring**
- **On-demand reporting engine – vendor performance**



Measure performs against SLA - get visibility to data that drives key performance indicators (KPI) in Red/ Amber & Green spotlights.

Contractual portal - many a times, client and vendor relationship organically grow and as a result leads to several amendments to contractual agreements, PvTRACE centralizes all the contracts and alerts on upcoming renewals and actions.

Measure success of audits & inspections - get visibility to audit report details capturing major, minor and observational findings.

Trend analysis - PvTRACE allows us to track corrective & preventive actions associated. PvTRACE will ultimately enable us to generate a trend analysis reports, that will ensure there are no repeated errors

"Innovative Technology developed in collaboration with our customers for the operational challenges faced by our customers."

Live data & transparency - real time access to stakeholders to satisfy both client and regulatory obligations

Training module - provides training module, with visibility to SOP(s) that are in scope, roles, and training matrix.

communication, portals or governance. Or indeed, just ensuring the regulatory agency can be satisfied that the right level of transparency, oversight, and communication exists between the service provider and client."

Bioclinica continues seamlessly to transition towards mature client engagements of more than five-to-ten years' duration. These can expand in scope as client confidence grows through experience of delivery excellence.

A strategic relationship also allows for cross-pollination of expertise and experience into other verticals when the service provider is seeking business from new clients, observes Dr Preeti Verma, Bioclinica's head of delivery and operations, drug safety and MICC. "For example, we are a major player in case-processing. But because of the quality and timeliness of the work we've undertaken for several of our clients, we've been able to support them in other areas such as aggregate reports or signal detection."

Moreover, end-to-end outsourcing favors consistency of delivery, to the benefit of both clients and regulators. "In a vast number of instances, we have seen that the larger pharmaceutical companies tend to outsource case processing to several different vendors," Verma points out.

"They may end up doing cases with different conventions and different databases. One thing that happens during inspections is there is a critical finding and no single point of access to all the safety data. These difficulties, coupled

with our solid reputation, have enabled Bioclinica to achieve the status of sole service provider for a number of companies that have transitioned away from multiple providers."

TRUST, TRANSPARENCY AND COLLABORATION

End-to-end outsourcing cultivates a relationship of trust, transparency and strategic collaboration. This relationship expands to the mutual benefit of both vendor and service provider, through cost-efficiency, exchange of knowledge and best practices, data integration, sustainability, and consistency of delivery.

"A good service provider doesn't just deliver in-scope activities," Qureshi explains. "Really, we should be utilized fully by our clients to support them in sharing best practices. That is particularly the case when we are working with over 50 other clients in the safety domain."

One service that Bioclinica provides in this respect is a regular trend analysis for all of its clients, "Every quarter we ask, 'what are the top three pain points for you? What's keeping you awake at night?'," Qureshi notes. "Then I'll give them an update: 'this is what other people are saying, or this is how other people are managing these issues', but making it bespoke to our clients."

That kind of holistic, cumulative exchange, building on mutually recognized interests, also puts both parties in a better position to endure shocks such as the current coronavirus pandemic. "We have been able to deliver for our clients with no compromise to their compliance and quality as a result of COVID-19," Qureshi points out. "Having a strategic relationship means that in situations like COVID-19, you can really see how reliable your partner is."

At a time when all health stakeholders are under intense pressure, the benefits of end-to-end services really come into focus. "A good relationship that expands organically can stand the test of time," Qureshi comments. "Where you have investment in that relationship in terms of, not necessarily money, but time, respect, communication and transparency, there's an expectation but also a genuine desire to ensure we do not fail our clients."

STRATEGIC IMPERATIVE

Pharmaceutical companies will continue stepping up their efforts to unlock cost-efficiencies and economies of scale in a marketplace where drug safety is an ever more pressing concern. In this demanding environment, end-to-end outsourcing of pharmacovigilance activities needs to become a central tenet of strategic thinking and planning.

Long-term strategic partnerships with a broad-ranging, knowledgeable and flexible service provider such as Bioclinica give these companies the reassurance that their safety needs are in experienced, capable and consistent hands. The same relationships supply the competitive advantage of both knowledge exchange and the opportunity to streamline and consolidate valuable internal resources.

This is about making the best use of available expertise inside and out. Then companies can focus even more intently on discovering, developing and marketing innovative medicines of real and lasting benefit to patients.

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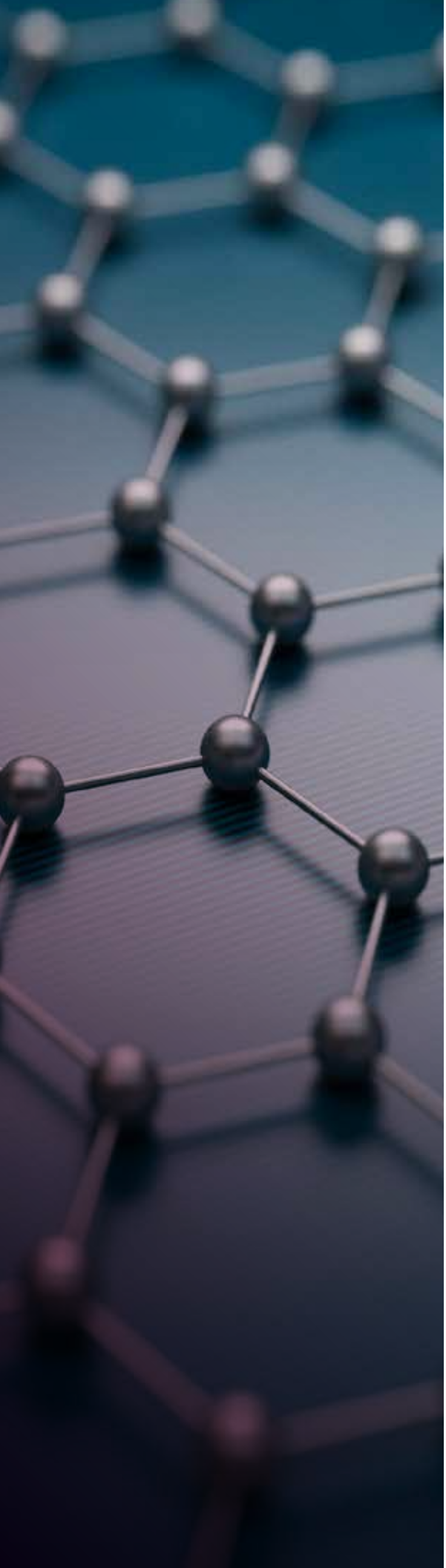

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- Drug Safety Solutions
- Medical imaging
- Cardiac safety
- Clinical adjudication
- Randomization and trial supply management and optimization
- Electronic and eSource data capture
- Site payments and budget forecasting
- Trial management solutions

For further information go to: **www.bioclinica.com**

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