CORPORATE FINANCE

MAY INSIGHTS PAPER: PHARMACOVIGILANCE

Navigating the complicated regulatory backdrop of drug safety – the importance of pharmacovigilance

Market overview

Rapidly evolving industry driven by an expanding drug development pipeline, necessitating effective scrutiny and investment into drug safety assessment and reporting

Increasing prevalence of Adverse Drug Reactions (ADR's) combined with the growing complexity of new products and stringent regulatory environment driving demand for specialist pharmacovigilance providers

Consolidation opportunities in a market made up of larger Contract Research Organisations (CROs) and an increasing number of specialist pharmacovigilance providers

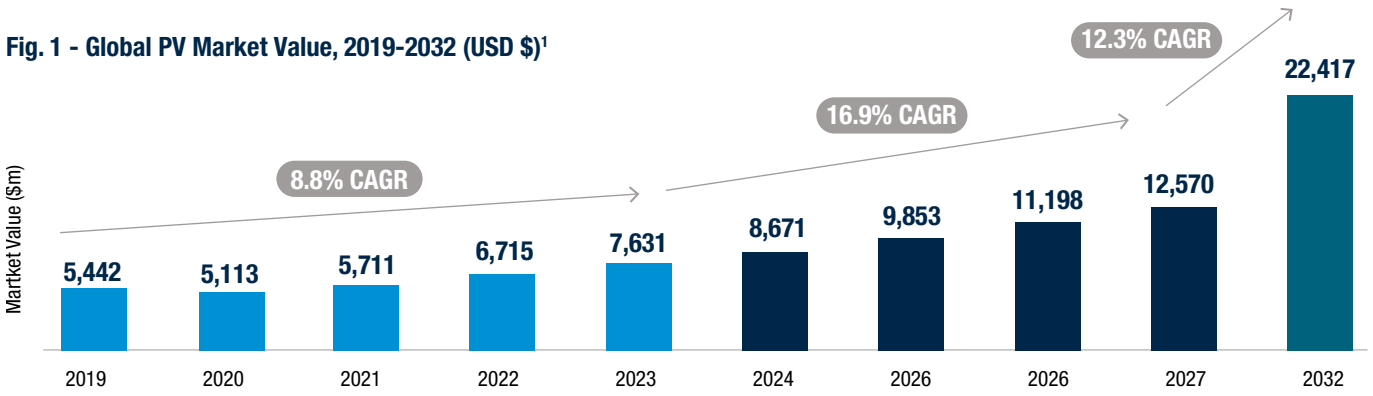
Opportunities to leverage new technologies (such as AI) revolutionising the sector, driving future growth, high multiples and opportunities for M&A

Pharmacovigilance – a complex but crucial factor in the drug development roadmap

Pharmacovigilance (PV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. It encompasses the monitoring of pharmaceutical products once they are on the market to ensure their safety and efficacy. This involves collecting and analysing data on ADRs and other drug-related issues from Healthcare Professionals (HCPs), patients and clinical studies.

By maintaining rigorous drug safety standards, PV plays a crucial role in public health and regulatory decision making. The global PV market is experiencing significant growth and is estimated to be c.$7.6 billion in 2023, having grown at a CAGR of 8.8% over the past 5 years, and is expected to more than double to $22bn in 2032[1]. This growth is being driven by the increasing prevalence of chronic diseases, the rising complexity of drug safety regulations, and the growing need for safer therapeutic practices.

Fig. 1 - Global PV Market Value, 2019-2032 (USD $)[1]



Source: [1]The BRC - Pharmacovigilance Global Market Competitor Report 2023

Fuelled by increasing ADRs due to drug complexity and consumption volumes supported by stringent regulatory requirements, the PV market has experienced significant growth

As we have previously touched on in our **Outsourced Pharma Services Insights Paper – January 2024**, the broader outsourced pharma services market has experienced significant growth in recent years, driven by the increased volume of drugs in development and the pharmaceutical industry's increasing focus on core competencies and cost efficiency.

Within the wide-spanning outsourced pharma services landscape, PV has established itself as a core component of the overall drug development pathway amidst a backdrop of rising ADR's and increased levels of scrutiny from both regulators and public health bodies. ADRs have increased in prevalence given the rising age of the population, increased use of drugs and the ever-growing and increasingly complex drug development pipeline. In research published by the BMJ, ADRs represented approximately 6.5% of UK hospital admissions back in 2004, with recent estimates suggesting that this figure has now reached 15.6%.[2]

The strong recent growth in the PV space has been driven by the following market trends:

1. Growing levels of drug consumption with increasing complexity of drugs being developed

The rise in chronic diseases such as cancer, diabetes, and cardiovascular disorders has led to an increase in drug consumption across the globe, driving a rapidly growing drug development pipeline with more complex therapeutics coming to market. This increasing volume and complexity of drugs in development (including the rising demand for personalised medicine) has led to greater likelihoods of unforeseen side effects and interactions, leading to an increased number of ADRs. There has also been growing public awareness regarding drug safety following on from greater heath literacy post-pandemic, resulting in increased levels of scrutiny around drug-safety from consumers and regulators alike.

Effective testing during the pre-clinical and clinical phases of the development pathway improves the overall drug safety profile, further contributing to the success of a new drug launches, driving demand for specialist PV providers.

2. Increasingly stringent regulatory mandates and complex compliance requirements

The regulatory landscape has grown in complexity, stimulated by the growing number of ADRs. In addition, Governments and regulatory bodies worldwide, such as the FDA (Food and Drug Administration) in the US, the EMA (European Medicines Agency) in Europe and the MHRA (Medicines and Healthcare products Regulatory Agency) in the UK, have established protocols for monitoring drug safety - an example being the Yellow Card reporting scheme used by the MHRA. A number of regulatory authorities also explicitly state the requirement to operate a PV system, such as the Good Pharmacovigilance Practices (GVP) in the European Union.

Drug developers are therefore required to undertake a holistic assessment of safety post-development which necessitates the need for effective data capture and robust monitoring. As the scale of these requirements continues to grow, pharma and biotech companies are increasingly turning to specialist PV providers to ensure the high level of regulatory compliance required is met.

3. Technological advancements driving efficiencies in the PV market

There is an abundance of opportunities currently present within the PV discipline to leverage advancements in technology in order to drive efficiencies within incumbent processes. PV and safety reporting in the past has been a laborious and process-heavy function, bottlenecking development timetables and offering limited scope for more granular analysis of safety data.

In the modern world of PV, integration of Artificial Intelligence (AI) and Machine Learning (ML) is enhancing both the efficiency and accuracy of drug safety reporting and monitoring. Specialist, technology-driven providers of PV have witnessed significant growth in demand as developers seek opportunities to optimise development timetables through improvements in drug safety data collection.

4. Continued trend of outsourcing in the pharma services industry, including of PV services

The global pharmaceuticals industry continues to favour outsourcing a number of elements within the drug development value chain, motivated by cost efficiency, scalability and ability to leverage specialised experience and expertise. The PV industry has followed suit, with specialist PV providers offering clients the ability to navigate complicated drug safety requirements, reducing costs and ensuring drug safety and efficacy.

Source: [2]BMJ Vol 12, Issue 7 – Adverse drug reactions, multimorbidity and polypharmacy

A market ripe for consolidation; the rise of specialised PV providers

As awareness around the importance of PV has increased in recent years, there has been an emergence of specialised PV service providers. Whilst many pharma companies continue to conduct their own PV activities through dedicated in-house PV departments which allows them direct control, confidentiality and seamless integration with other internal departments, the provision of these services are resource intensive and require extensive compliance management due to the regulatory complexity often making the handling of large volumes of data and reports challenging. As a result, there has been an increasing trend (as with other areas of the pharma industry) to outsource this service provision to dedicated PV firms with specialised expertise and experience which allows for scalability and flexibility as well as cost efficiency.

The outsourced PV sector is populated by several key players varying from large CROs and specialised PV service providers. Leading CROs with an established offering in the PV space include IQVIA, Ergomed, Parexel, Covance (Labcorp), PRA Health Sciences and Icon plc. Their PV services sit alongside a wider pharma services offering which can include clinical trial engagement, regulatory affairs, data management and biostatistics and medical writing, offering a 'one-stop-shop' option for the pharma and biotech industry.

A multi-service CRO with a strong PV offering is the leading British biopharma services provider Ergomed, which was recently taken private by the European private equity firm Permira. Ergomed announced strong growth within its PV division in the six months to June 2023, with revenues up by 9% to £38.7m[3].

Due to the growing complexity and regulatory demands of drug safety monitoring, the market has experienced an emergence of smaller, specialist PV providers to compete alongside these larger CROs. These specialist firms tend to provide a more bespoke offering, with competencies in specific therapeutic areas or geographies at a smaller scale relative to the larger CROs, in addition to offering further consultancy services in the regulatory space. The emergence of specialist providers has provided excellent consolidation opportunities for the larger CROs in the sector over recent years, driven by the need for comprehensive service offerings, enhanced technological capabilities, and the ability to operate on a global scale as larger companies absorb smaller firms to expand their capabilities and market reach.

As the pharmaceutical industry continues to evolve and pharma and biotech companies continue to focus on the outsourced model, the role of these specialist firms will likely become even more critical in safeguarding public health and therefore further consolidation in the market is expected.

Buyer Group	A&M view on acquisition capacity	Rationale	Examples of recent acquirors
CROs with an established PV offering		■ Potential to expand existing PV capabilities and capture additional market share ■ Acquisition of tech-enabled platforms provide opportunities to grow competitive advantage	ERGOMED, CLINIGEN, IQVIA, parexel
Wider outsourced service providers		■ Opportunity to acquire PV expertise/ tech-enabled platforms to expand current services offered ■ Ability to unlock further value from existing customers through supporting on a greater number of components of the drug development lifecycle	charles river, SYGNATURE DISCOVERY
Wider consultancies*		■ Consultancies currently offering PV look to benefit from capability expansion and increase of market share ■ Further opportunity for established consultancy businesses seeking opportunities to expand into the lucrative pharma outsourced services industry to diversify existing service offering	accenture, cognizant, Deloitte.
Private Equity		■ Highly desirable given the high-growth industry profile and resilient returns ■ Significant potential for further bolt-on opportunities within the mid-market	KESTER CAPITAL, STANLEY CAPITAL, LDC, gcp, Vespa Capital

**There are no recent transactions within PV announced by wider consultancies, however many of them have established PV offerings.*

Source: [3]Ergomed Interim Results 2023

Strong appetite for M&A with interest from both Strategic and Financial buyers

Alongside the wider outsourced pharma services ecosystem, the PV M&A market demonstrated significant operational resilience in the wake of the macroeconomic pressures felt towards the later half of 2023, where a combination of factors such as rising interest rates, above-average inflation and supply chain challenges placed significant burden on the deal market in the short term.

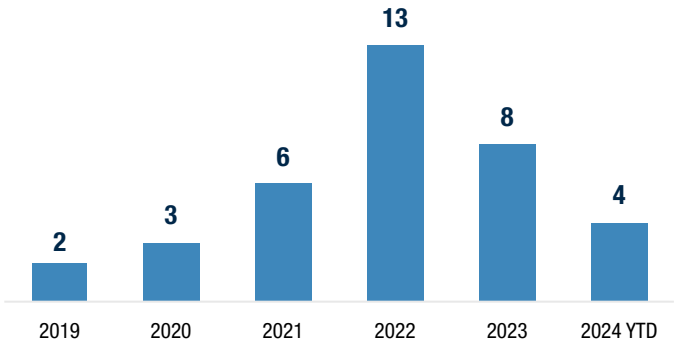
Transaction volumes within the outsourced PV sector experienced a boom post-pandemic, with a total 19 transactions recorded over 2021 and 2022. There were a number of transactions undertaken by strategic acquirors over this period, as larger providers sought opportunities to gain market share, demonstrating the trend towards broader industry consolidation. Several of these corporates also sought M&A as an opportunity to expand capabilities into drug safety monitoring and to bolster existing operations to leverage operational efficiencies, driving down the cost of monitoring and reporting.

Other drivers within the sector include the push for more sophisticated, technology-driven approaches to drug safety. Tech-driven approaches in ADR monitoring has been proven to drive improvements in both the speed and accuracy of drug safety assessments. This has made smaller tech-enabled providers key targets for larger corporates as it would present a lower cost and more easily integrated approach to building their own technology. An example of this is the recent acquisition of the Danish PV platform Insife ApS by Qinesca Solutions, a specialist in technology-led end-to-end pharmacovigilance solutions. The acquisition allows Qinesca to access Insife's in-house developed digital breakthrough HALOPV, which offered users the ability to manage all global PV activities, including workflow solutions and automation capabilities, through a single application.

Private Equity (PE) firms also continue to show strong interest in the outsourced pharma services space and have continued to drive strong multiples in the sector. PE firms have increasingly focused on the more specialised, high value and tech-enabled service offerings in the market in their search for innovative, value-added and scalable assets. For example, last year Kester Capital announced its acquisition of the German provider of Good Clinical/ Pharmacovigilance Practice (GCP/GVP) consulting services – GXP Engaged - marking Kester's sixth acquisition within the Life Sciences space with the team noting strong market tailwinds supporting the transaction.

As noted previously, the pressures felt by macroeconomic shocks caused an abrupt softening of transaction volumes towards the end of 2023. Despite this, there were eight transactions within the outsourced PV services sector that completed in the year, one of which from PE, with a further four in the first half of 2024. This demonstrates the resilience of the sector against slowdown, attracting both strategic and financial investors alike. Further consolidation is set to continue, driving up demand and leading to potentially significant valuations on offer.

Fig. 3 – PV Transactions by Year (2019 – 2024 YTD)[4]



Selected precedent transactions

Date	Target	Aquiror	Deal rationale
Apr-24	insife	Qinecsa	The acquisition of Insife, which has developed a digital PV platform, bolsters Qinesca's technology-led PV capabilities.
Feb-24	CommercialEyes	PLG ProductLifeGroup	The acquisition of Commercial Eyes, one of Australia's leading PV providers, establishes a foothold for PLG in the Asia-Pacific market.
Sep-23	GXP Engaged Auditing Services	KESTER CAPITAL	This marked Kester's sixth investment within the Life Sciences sector which broadened its portfolio offering and capabilities in the industry.
Aug-23	NDA	SSI Strategy	The merger between Amulet Capital-backed Life Sciences consultancy SSI Strategy and PV specialist NDA Group created an industry-leading provider of end-to-end solutions for drug developers.

Source: [4]MergerMarket, A&M Analysis

The specialised nature of the PV service offering into the high value pharma end-market drives strong multiples in the sector

In line with the broader outsourced pharma services industry, businesses operating within the PV market continue to demonstrate strong valuations owing to its specialised nature feeding services into the pharma industry whilst also offering significant opportunities for tech-enablement.

Specialist PV providers can expect to command solid valuation multiple over other industries given the demonstrated resilience in M&A activity against macroeconomic shocks and the lucrative opportunities available to investors seeking to benefit from the strong tailwinds currently present within this industry.

As can be seen in the table below, the relevant quoted company peer-group contains both specialised providers of outsourced services to the life sciences sector as well as established consultancies offering PV. Multiples demonstrated are attractive, ranging between 9.0-18.0 x.

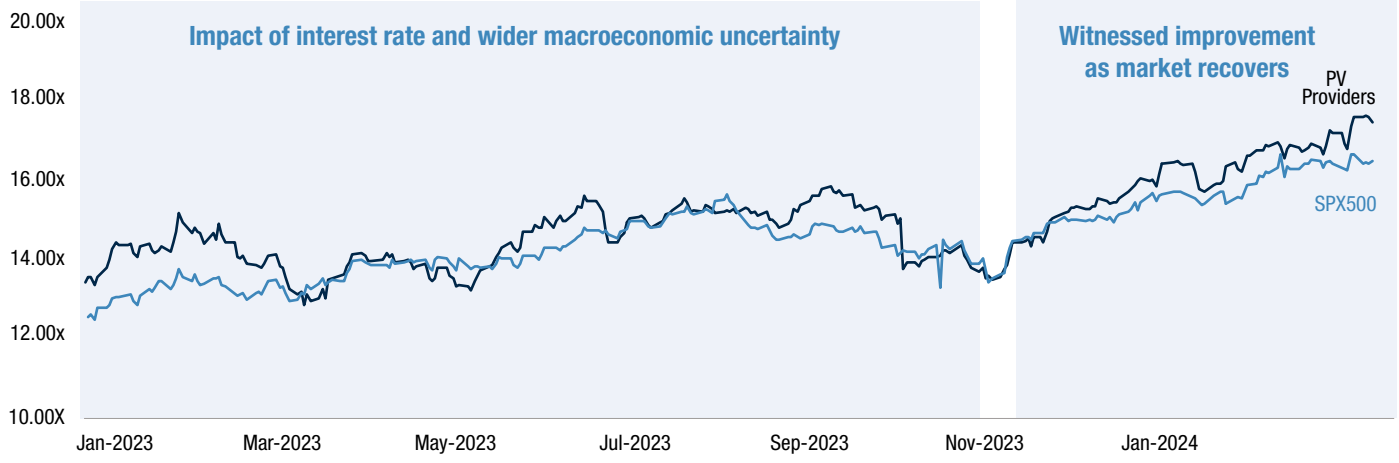
Recent transactions undertaken within the sector track at a similar level to the listed peer-group with more specialised and tech-enabled offerings demanding higher multiples. Whilst limited transaction multiples are publicly available, general trend analysis shows multiples in this industry averaging in the 20x region (to note this is based on listed businesses who demand a premium).

For example, Thermo Fisher acquired PPD (offering a range of pharma outsourcing services including PV) for $17bn representing an EBITDA multiple of 24.2x. A more recent example was the sale of Ergomed to Permira announced late last year. Ergomed, which provides PV alongside its' broader pharma outsourced services offering, was acquired for 24.0x EBITDA. There are limited publicly available multiples for businesses of a smaller scale operating in the PV space but we would expect these to command multiples in the mid teens.

Selected Public Comparables (as at 13 May 2024)

Company	Market Cap (£bn)	Enterprise Value (£bn)	Implied EV/EBITDA multiple
ICON plc	17.3	20.4	16.0x
IQVIA Holdings Inc	30.0	39.9	18.0x
Wipro Limited	19.4	17.9	10.7x
Cognizant Technology Solutions	26.7	26.0	9.2x
Accenture plc	162.2	158.1	17.9x

Historical EV/ EBITDA multiples



Source: Company filings and A&M Analysis. Contact A&M for a broader discussion and more detailed analysis on valuation.

An exciting outlook for future growth with demand for PV set to drive M&A volumes

With the pre-existing strong tailwinds expected to continue to drive volumes of PV requests, the outsourced PV market is expected to continue on its strong growth trajectory, laying the foundations for significant deal activity as the market continues to consolidate.

With volumes of drugs being developed showing no signs of slowing, combined with the increasing drug complexity and rise in personalised medicine requiring a deeper understanding of drug safety and efficacy, PV is likely to become even more critical. With the additional challenges provided by the regulatory landscape, developers will continue to seek support from expert PV providers able to navigate the compliance requirements to mitigate risks and further improve the drug safety profile.

AI and machine learning offers an exciting opportunity for existing service providers to revolutionise their offering by enhancing the efficiency, accuracy, and speed of ADR detection and reporting. AI algorithms can analyse vast amounts of data from diverse sources to identify potential safety signals more quickly than traditional methods whilst machine learning models can predict and prioritise ADRs, reducing the time and resources required for manual data analysis. Moreover, AI-driven automation streamlines routine pharmacovigilance tasks, such as data entry and case processing, allowing pharmacovigilance professionals to focus on more complex analytical activities. This transformation not only improves drug safety monitoring but also accelerates the development of safer pharmaceuticals, ultimately enhancing patient outcomes and regulatory compliance. As a result, it is likely that tech-enabled PV providers will dominate market share.

Opportunities to acquire high-growth, technology-backed PV platforms within the mid-market is expected to drive a surge in M&A activity from acquirors seeking to grow capabilities and benefit from economies of scale. As such we expect to see considerable consolidation in coming months.

How can A&M help you

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