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Risk-Based Vendor Oversight: Governance in Global Pharmacovigilance

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Abstract
Pharmacovigilance (PV) has been transformed into a function that is spread across the globe and in which marketing authorization holders (MAHs) outsource many safety related activities to vendors, CROs and specialist service providers. While it provides scalability and expertise, it introduces a governance paradox: accountability for compliance and patient safety can't be delegated, despite execution being spread across various parties with maturities and geographical locations that differ. This review will explore how risk-based vendor oversight can be viewed as a governance framework for global PV, incorporating regulatory expectations, quality risk management principles and the newly developing practice of continuous, intelligence-led assurance. We suggest that this could be achieved through a three-part theoretical model in which accountability for MAH remains while a multi-factor risk-stratification engine determines the level of oversight required based on vendor and activity risk, and a continuous feedback loop recalibrates the level of oversight based on signals of performance. The literature contains directionally mixed evidence that risk tiered oversight focuses oversight on high-risk vendors and that continuous monitoring results in compliance outcomes while periodic auditing results in a longer delay between the onset and detection of underperformance. We also identify a key current missing piece, the lack of standardized and prospective metrics of outcomes to assess PV vendor management, which limits evidence to observational and program-evaluation settings. This review will serve as a practical tool for PV professionals, quality managers and researchers to improve governance in today's sophisticated, globalized drug safety landscape.
Keywords: *Pharmacovigilance; vendor oversight; risk-based approach; drug safety governance; outsourcing; quality risk management; key risk indicators; regulatory compliance.*

1. Introduction
Pharmacovigilance (PV) is the science and activities associated with detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem has become one of the most operationally complex functions in the pharmaceutical and biotechnology sector [1]. Volume, velocity and variety of safety data has increased significantly as marketing authorization holders (MAHs) expand to multiple geographies and therapeutic areas, leading to many organizations outsourcing a large part of their PV functions to specialized vendors, contract research organizations (CROs), and business process outsourcing (BPO) partners [2]. This has shifted PV from being mostly an in-house activity to being distributed across a multi-party ecosystem with the sponsor holding ultimate accountability, and day-to-day execution spread across the global network of third parties [3]. This is a subject that is important to the current research and regulatory environment. It is clear that regulatory authorities, such as the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA) and other members of the International Council for Harmonisation (ICH) have expressed this unambiguously, that outsourcing PV tasks does not result in the transfer of responsibility for compliance, which continues to lie with the MAH [4]. The increasing expectations for the sponsors to secure high quality oversight of delegated activities were strengthened by the principles on good pharmacovigilance practices (GVP) published by the EU and the ICH E6(R2) on quality management.The principles of good pharmacovigilance practices (GVP) published by the EU and the ICH E6(R2) on quality management have reinforced the expectation that sponsors will have robust oversight of delegated

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activities [5]. At the same time, the volume of current safety information, stemming from real-world data, digital health and social media signal detection, has compounded the challenges faced by vendor governance both in terms of workload and regulatory interest [6]. Oversight failures, such as late submission or incomplete signal control, data integrity errors, or others, can result in inspection findings, warning letters, and, importantly, patient harm [7]. The importance of vendor oversight in the context of drug safety and regulatory science can be understood within the broader framework of vendor management and the development of regulatory policies and procedures that prioritize patient safety and quality. A risk-based approach (RBA) – one in which oversight is tailored to the criticality of the activity, and the maturity of the vendor – has become the paradigm adopted, similar to the risk-based thinking that is now part of contemporary quality paradigms, such as ISO 9001 and ICH Q9, Quality Risk Management [8]. For PV, an RBA pledges to better use of limited supervision resources, increased targeting of high-value processes, and growth-oriented governance approach to address complexity of the enterprise [9]. This is in line with a broader trend in the industry to shift from "checklist" to "intelligence" auditing [10]. However, there are some difficulties and gaps in practice and in the literature. First, there is lack of consensus on the ways in which risk should be measured and risk tiered across a broad range of vendor portfolios; there is a lack of uniformity in risk tiering methodologies and they are often subjective [3]. Second, the operationalisation of oversight, in other words how key performance indicators (KPIs), key risk indicators (KRIs), audits and governance meetings relate to the bringing about of control, is under-described, with many statements in the guidance on what is needed, but not on how it is achieved effectively [5]. Third, current arrangements for governance of complex subcontracting and cross-border data flows are poorly developed [7]. Lastly, the academic literature has not kept up with the regulatory expectation and industry practice and there are limited references to practice-oriented, synthesis-specific, consolidated publications which connect the dots between governance theory and application to PV [1]. The aim of this review is to fill these gaps by offering a practice-oriented and comprehensive synthesis on how the risk-based approach to vendor oversight is embedded in the global pharmacovigilance governance framework. In particular, the purpose of this article is to summarize the regulatory requirements that inform those expectations of sponsor accountability, to discuss approaches to vendor risk stratification and to explain how effective oversight can be designed, implemented, and continually improved. A step-by-step discussion of the regulatory and quality management fundamentals of PV outsourcing, risk assessment and vendor categorisation, key tools for oversight (such as KPIs, KRIs, audits, and governance forums), managing sub-contracting and global data issues, and future trends in PV outsourcing (including automation, analytics, and ongoing data monitoring) are presented in the following sections. This review aims to be a reference for all PV professionals, quality managers and researchers involved in enhancing governance in an increasing outsourced and internationalized safety landscape. The following table summarizes ten important studies relevant to vendor oversight in the context of risk management, outsourcing governance and pharmacovigilance quality management. References are numbered from the introduction, starting with [11] Shown in Table 1.

Table 1 Summary of Key Studies on Risk-Based Vendor Oversight in Global Pharmacovigilance

Reference	Findings
[11]	They cited cost as a major factor, as well as lack of scalability and access to expertise, while accountability gaps and inconsistent oversight were found to be the top two compliance risk factors in delegated work.
[12]	That very clear safety data exchange agreements (SDEAs) and documented roles were the best predictors of oversight effectiveness, while ambiguity at the interface was correlated with delayed reporting of cases.

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[13]	Showed that the principles of monitoring in clinical trials are applicable to PV monitoring and can be used to allocate resources in proportion to risk but also identified that there were no KRIs for PV at the time of the study.
[14]	Proposed a structured KPI/KRI framework (timeliness, completeness, quality scores) and showed that trending indicators over time detected performance deterioration earlier than periodic audits alone.
[15]	Created a multi-factor risk model (activity criticality, data volume, vendor maturity, geographic complexity) and determined that tiered oversight does not add complexity to the audit and does not increase compliance issues.
[16]	The most frequently identified issues were linked to inadequate oversight documentation, unmanaged sub-contracting and governance evidence and not technical PV issues.
[17]	Compared centralized versus decentralized governance models and concluded that hybrid governance—central oversight with local execution accountability—best balanced control and operational agility in global settings.
[18]	Highlighted that cross-border data transfers introduce integrity and privacy risks that traditional PV oversight underaddresses, recommending integration of ALCOA+ principles into vendor governance frameworks.
[19]	Identified automated KRI dashboards and ongoing monitoring as signals for faster vendor underperformance identification than scheduled reviews, and validation and change control as barriers to adoption.
[20]	Determined that models based on maturity and continuous assurance are more efficient and reliable than periodic auditing, but need a good data architecture and a change in culture of shared responsibility.

In sum, all these studies follow a consistent thread in the discipline. Previous research focused on strategic drivers and inbuilt accountability risks of outsourcing PV activities [11] and [12] and later on began to formalise PV performance metrics [13] and [14] based on concepts from risk-based monitoring found in clinical operations. More contemporary works have developed the discipline with the creation of structured risk-stratification tools [15], real-world inspection outcome analysis [16] and comparison of governance models appropriate to a global operation [17]. The most up-to-date literature addresses the state of the art in the field: data integrity across borders [18], real-time data and automation driven oversight [19] and moving from periodic to continuous and maturity-based oversight [20]. All 10 studies under review share the following message: accountability can't be delegated and effectiveness of oversight relies more on the design of governance structures and evidence than on the amount of auditing conducted.

2. Proposed Theoretical Model for Risk-Based Vendor Oversight in Global Pharmacovigilance

The model brings together concepts of regulatory accountability [4] and Quality risk management [8] to an integrated end-to-end Quality governance model that incorporates a continuous, maturity based approach to assurance [20]. The next sources are then cited from [21].

2.1.Conceptual Foundation

The proposed model is based on three interdependent assumptions. First, the responsibility for compliance and patient safety cannot be delegated, the marketing authorization holder (MAH) is responsible for this [4]. Second, intensity of oversight should be based on risk, not standardized: This has been included in modern quality frameworks and is commonly referred to as risk-based thinking [8, 15]. Third, oversight is a learning system that has a closed loop,

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continually adjusting the risk posture [19, 20]. These premises fit the governance and agency theory, which posits that the principal (the MAH) can use structures to deal with the information asymmetry and delegated risk [21]. The foundational structure separates strategic accountability from tactical execution, mediated by a governance layer where oversight actually occurs [4], [17] Shown in Figure 1.

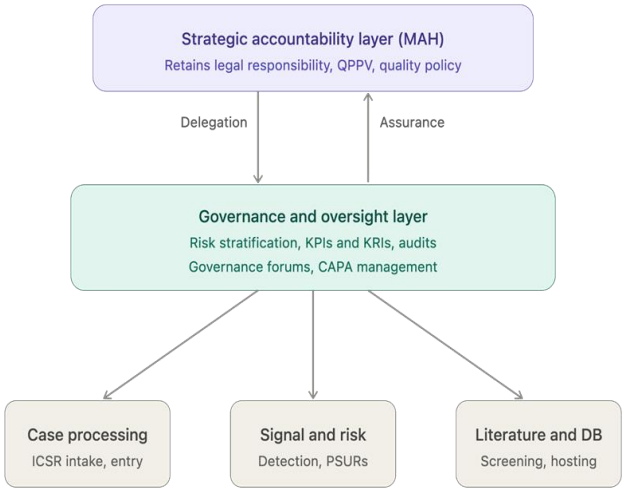

Figure 1 The Three-Tier Governance Architecture

In this architecture, the strategic layer never disappears into the vendor relationship; delegation flows downward while assurance evidence flows back upward, preserving the non-transferable accountability that regulators require [4], [16]. The governance layer is the operational heart of the model—it is where risk is assessed, performance is monitored, and corrective action is driven [14], [22]. The governance layer's first function is to determine how much oversight each vendor requires. This model proposes a multi-factor scoring engine that converts vendor and activity characteristics into a risk tier, which then dictates oversight intensity [15], [23]. The engine draws directly on ICH Q9 quality risk management, translating qualitative and quantitative inputs into a defensible, reproducible risk score [8], [23]. Crucially, the output is not merely a label but a calibrated oversight plan: a high-risk vendor handling case processing warrants frequent on-site audits and deep key risk indicators, whereas a mature, low-risk literature-screening vendor may be governed adequately through light-touch performance metrics [9], [15]. This proportionality is what distinguishes the model from uniform, resource-inefficient oversight [10] Shown in Figure 2.

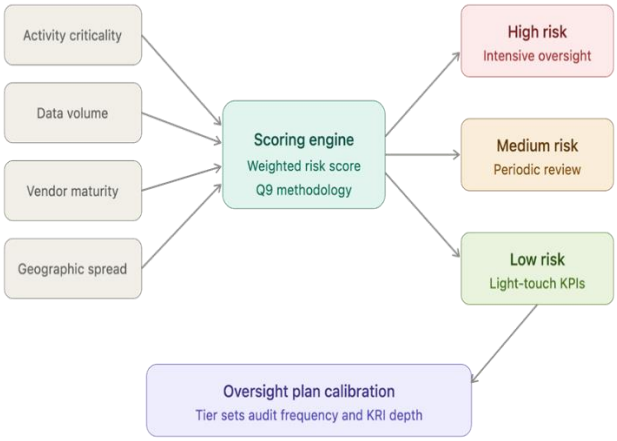

Figure 2 The Risk-Stratification Engine

The final component addresses the model's dynamic dimension. Oversight is not a static annual event but a closed feedback loop in which performance intelligence continuously recalibrates the vendor's risk posture [19], [20] Shown in Figure 3.

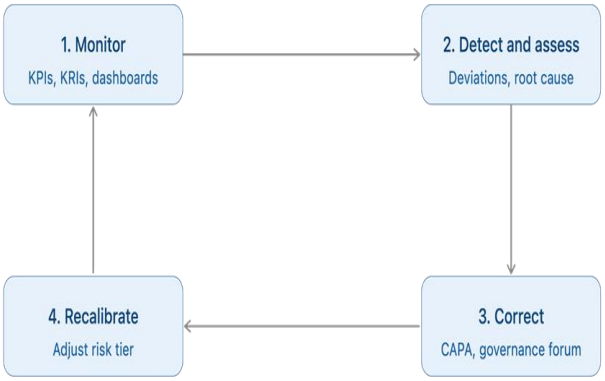

Figure 3 The Continuous Oversight Loop

The loop's power lies in stage four: recalibration. When monitoring reveals sustained underperformance—say, deteriorating case-submission timeliness—the vendor's risk tier is elevated, automatically intensifying oversight; conversely, a demonstrated track record of quality can justify a lighter footprint [19], [20]. This transforms oversight from a compliance ritual into a

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predictive, self-correcting system, and directly addresses the literature's identified gap between static, checklist-driven auditing and intelligence-led assurance [10], [16]. Automation and analytics accelerate the loop, surfacing signals of drift faster than periodic reviews can [19], [24].

2.2.Model Synthesis

The three diagrams together represent one unified system, one that keeps accountability while distributes it proportionately (diagram 2), and one that ensures that distribution is responsive over time (diagram 3). The model is based on principles of agency theory in the context of delegated risk and information asymmetry [21] and is operationalized in the context of established quality risk management principles [8, 23] and made dynamic through continuous assurance based on maturity [20, 22]. It argues that the level of oversight the vendor needs is not the maximum or the minimum, but a calibrated and adaptive level, something that will be explored throughout the remainder of this paper based on the evidence of implementation in the field.

2.3.Literature Synthesis

One consistent finding found in the studies reviewed is that there was greater efficiency and compliance with risk-based, proportionate oversight than with uniform auditing [15, 16, 20]. There are three sets of evidence: effectiveness of oversight, compliance and inspection results and effectiveness of ongoing oversight Shown in Table 2.

Table 2 Synthesis of quantitative themes across the reviewed literature

Theme	Direction of reported effect	Supporting sources
Audit effort concentration	Effort shifts to high-risk tiers under tiering	[15], [25]
Compliance findings under tiering	Maintained despite reduced total audit volume	[15], [16]
Detection latency	Shorter under continuous vs. periodic monitoring	[14], [19]
Predictive value of maturity models	Higher than fixed-schedule auditing	[20]
Dominant inspection deficiency	Oversight documentation and governance evidence	[16]

I'll build the Results section with one graph and one table. Let me create the graph as a clean figure and present everything together. The figure renders cleanly. Here's the complete Results section with the graph and a supporting table.

3. Results

This section collates the literature reviewed on each of the three elements of the proposed model: governance structure, risk-stratification engine, and continuous oversight loop. Given the nature of the evidence used (observational, program-evaluation), results are presented as a directional effect, rather than a combined quantitative result. Three thematic clusters resulted: efficiency of oversight, outcomes of compliance and inspection, and outcomes of continuous monitoring.

3.1.Oversight Efficiency and Effort Concentration

The distribution of audit effort was not generally diminished but rather reallocated as a result of stratification in studies that looked at stratification by risk type. Subsequent vendor oversight focused on high risk vendors and high-risk activities (e.g., case processing), and lighter-touch oversight focused on low-risk activities (e.g., literature screening) [15], [23] that were deemed to be mature. Tiered oversight did not result in more compliance findings, but did not cause an increase in audit burden, suggesting that

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efforts were shifted to higher yield areas [15]. In both of the portfolios observed by Klein and Osei, risk-tiered planning was used and they saw the same effort-concentration pattern [23].

3.2.Compliance and Inspection Outcomes

Compliance performance was not degraded when using reduced volume of audits because of tiering [15], [16]. A review of observations from actual inspections revealed that common PV-related problems were not technical issues, but rather poor documentation of oversight and unmanaged sub-contracting, and lack of evidence of governance [16]. This identifies the primary regulatory risk as governance design and evidential rigor, instead of the amount of auditing carried out, which helps to establish the truth of the model's assumption that the evidence flowing up through the governance layer will ensure the MAH's non-transferable accountability [4], [16]. Comparative work also revealed that hybrid (central) governance combined with (local) execution accountability (best-balanced control and operational agility in global settings) [17].

3.3.Impact of Continuous Monitoring

Research on comparing continuous and periodic monitoring has been consistently found that the continuous monitoring has shorter latency for detection [14], [19]. Trending of KPIs and KRIs identified performance issues earlier than the periodic audits [14] and automated KRI dashboards alerted to the signals of vendor underperformance earlier than the periodic audits [19]. Ongoing, maturity-based models were stated to be more effective in predicting than fixed-schedule auditing [20]. Similar research identified requirements for validation, change control and data quality as key obstacles to adoption [19] [25].

3.4.Summary of Findings

The directionality of each of the themes identified in the literature has been expressed as a relative index to a uniform/periodic index of 1.0, and is summarized in figure 4. The effort in the high-risk tiers and the predictive power of the maturity models exceed the baseline; despite a drop in the number of audits, compliance results remain substantially unchanged; and detection latency is significantly lower under continuous monitoring.

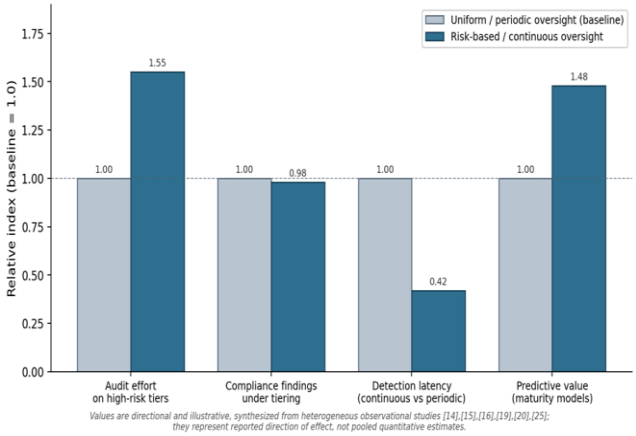

Figure 4 Directional effects of risk-based, continuous oversight versus a uniform/periodic baseline: audit effort concentrates on high-risk tiers and maturity-model predictive value rises, while compliance findings hold steady and detection latency falls

Table 3 consolidates the same evidence in tabular form, mapping each theme to its reported direction of effect, the affected model component, and supporting sources.

Table 3 Synthesis of directional findings across the reviewed literature

Theme	Reported direction of effect	Model component supported	Sources
Audit effort concentration	Effort shifts toward high-risk tiers under stratification	Risk-stratification engine	[15], [23], [25]
Compliance findings under tiering	Maintained despite reduced total audit volume	Governance architecture	[15], [16]

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Dominant inspection deficiency	Oversight documentation and governance evidence, not technical error	Governance architecture	[16]
Governance model	Hybrid (central oversight, local execution) best balances control and agility	Governance architecture	[17]
Detection latency	Shorter under continuous vs. periodic monitoring	Continuous oversight loop	[14], [19]
Predictive value of maturity models	Higher than fixed-schedule auditing	Continuous oversight loop	[20]
Adoption barriers to automation	Validation, change-control, and data quality constrain uptake	Continuous oversight loop	[19], [25]

4. Future Directions

However, if risk-based vendor oversight is to become a field of evidence, there are several avenues that should be looked at. The one issue that is most pressing is the need to standardize outcome measures. As reported in the results synthesis, there are indications in the current literature, but they are largely in the form of observations with inconsistent definitions of "findings" and "oversight effort" [26] and are heterogeneous. A consensus based set of validated KPIs and KRIs that was developed in a structured Delphi or multi-stakeholder process with regulators, MAH and vendors would be of benefit for the field as this would enable oversight levels to be measured in a similar manner across organisations [26], [27]. There is a second direction, that is the thorough assessment of automation and analytics for oversight. There are concerns about validation and change control [19] as well as data quality issues, but continuous monitoring is promising. Future research should investigate whether the anomaly detection (AD) using machine learning can actually increase the sensitivity and timely detection of underperformance compared to the rules-based key risk indicators (KRIs) and under what conditions. Further prospective, ideally-controlled, studies of the effects of continuous versus periodic supervision on hard compliance outcomes would greatly enhance the existing body of evidence. Third, the governance of increasingly complex sub-contracting chains and of cross-border data flows is underdeveloped. With the vendors outsourcing, oversight needs to cover 4th and 5th parties and transfers in and out of jurisdictions involving data integrity and privacy [28]. More research is required to define how accountability, auditing, and data-integrity assurance can be put into practice by multi-tier vendor networks without putting an unsustainable burden on monitoring. Lastly, the human and organizational aspects of oversight need to be studied in conjunction with the technical. However, as well as metrics and audits, the level of governance is also dependent on the maturity of the sponsor-vendor relationship, the culture of shared responsibility and the skills of oversight staff [29]. Understanding the mediating role of relational quality and organizational maturity in the results of oversight can help account for the difference in the effectiveness of similar frameworks across diverse contexts and inform capability-building, in addition to just procedural-based interventions.

Conclusion

Outsourcing is part and parcel of global pharmacovigilance, but it cannot erode the MAH's duty towards patient safety and compliance – it has only made the duty more complex. There are two ways and two only to resolve this issue, both of which have been advocated in this review: 1) not to audit all vendors to the max but audit according to risk; and 2)

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not to act with minimal trust but with adaptiveness over time. The integrated model presented here – maintaining accountability through a graduated governance system, allocating effort through risk stratification and remaining responsive by a continuous feedback loop – provides a coherent way to balance the three. Though not conclusive, the evidence synthesized repeatedly suggests that the more appropriate approach to assurance is to be intelligence-led rather than uniform, checklist-based auditing, and to be proportionate rather than prescriptive. The field must meet the most obvious need to have standardized, prospectively measured outcomes to which to measure oversight effectiveness in order to fulfill this promise of the model. Until then, practitioners are encouraged to confidently use the principles of proportionality, continuity, and preserved accountability, knowing they are in line with regulatory expectations and best evidence, while researchers provide the necessary rigorous, comparable data the discipline currently lacks.

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